

Title: Donna E. Shalala, Secretary of Health and Human Services, et al., Petitioners
v.
Illinois Council on Long Term Care, Inc.

Docketed:
January 12, 1999

Court: United States Court of Appeals for
the Seventh Circuit

Entry Date

Proceedings and Orders

Oct 30 1998 Application (98A367) to extend the time to file a petition for a writ of certiorari from November 11, 1998 to December 12, 1998, submitted to Justice Stevens.
Nov 2 1998 Application (98A367) granted by Justice Stevens extending the time to file until December 12, 1998.
Dec 2 1998 Application (98A367) to extend further the time to file a petition for a writ of certiorari from December 12, 1998 to January 10, 1999, submitted to Justice Stevens.
Dec 4 1998 Application (98A367) granted by Justice Stevens extending the time to file until January 10, 1999.
Jan 11 1999 Petition for writ of certiorari filed. (Response due February 11, 1999)
Jan 27 1999 Waiver of right of respondent John R. Lumpkin, Director of IL Dept. of Public Health to respond filed.
Feb 11 1999 Brief of respondent Illinois Council on Long Term Care in opposition filed.
Mar 18 1999 Reply brief of petitioner Donna E. Shalala, Secretary of Health and Human Services filed.
Mar 31 1999 DISTRIBUTED. April 16, 1999
Apr 19 1999 Petition GRANTED.
SET FOR ARGUMENT November 8, 1999.

May 27 1999 Order extending time to file brief of petitioner on the merits until July 2, 1999.
May 27 1999 Order extending time for filing respondent's brief on the merits to August 23, 1999.
Jul 2 1999 Joint appendix filed.
Jul 2 1999 Brief of petitioner Donna E. Shalala, Secretary of Health and Human Services filed.
Aug 2 1999 LODGING consisting of ten copies of amendments from the Federal Register/Vol. 64, No. 141, Friday July 23, 1999, submitted by the Solicitor General.
Aug 11 1999 Letter received from the Solicitor General.
Aug 13 1999 Brief amicus curiae of American Association of Homes and Services for the Aging filed.
Aug 23 1999 Brief amici curiae of American Medical Association, et al. filed.
Aug 23 1999 Brief amicus curiae of American Hospital Association filed.
Aug 23 1999 Brief of respondent Illinois Council on Long Term Care filed.
Aug 23 1999 Brief amici curiae of American Health Care Association, et al. filed.
Sep 7 1999 Record filed.
Sep 20 1999 Record filed.
Sep 21 1999 CIRCULATED.

Entry Date	Proceedings and Orders
Sep 24 1999	Reply brief of petitioners Donna E. Shalala, Sec., Health & Human Services, et al. filed.
Nov 4 1999	Motion of respondent for leave to cite additional authority in response to the reply brief of the Solicitor General filed.
Nov 4 1999	DISTRIBUTED. November 5, 1999 (Page 11)
Nov 8 1999	Motion of respondent for leave to cite additional authority in response to the reply brief of the Solicitor General DENIED.
Nov 8 1999	ARGUED.

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No.

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In the Supreme Court of the United States

OCTOBER TERM, 1998

DONNA E. SHALALA, SECRETARY OF HEALTH AND
HUMAN SERVICES, ET AL., PETITIONERS

v.

ILLINOIS COUNCIL ON LONG TERM CARE, INC.

*ON PETITION FOR A WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE SEVENTH CIRCUIT*

PETITION FOR A WRIT OF CERTIORARI

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QUESTION PRESENTED

Whether 42 U.S.C. 405(h), incorporated into the Medicare Act by 42 U.S.C. 1395ii, permits skilled nursing facilities participating in the Medicare program to obtain judicial review under 28 U.S.C. 1331 and 1346 (1994 & Supp. II 1996) to challenge the validity of Medicare regulations.

PARTIES TO THE PROCEEDING

Petitioners are Donna E. Shalala, Secretary of the Department of Health and Human Services and Anthony J. Tirone, Deputy Director of the United States Office of Survey and Certification, Health Standards and Quality Bureau, Health Care Financing Administration. Petitioners were named as defendants/appellees in the court of appeals. Both petitioners appear in their official capacities only. John R. Lumpkin, M.D., Director of the Illinois Department of Public Health, was also a defendant/appellee in the court of appeals.

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ILLINOIS COUNCIL ON LONG TERM CARE, INC.

ON PETITION FOR A WRIT OF CERTIORARI
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PETITION FOR A WRIT OF CERTIORARI

The Solicitor General, on behalf of the Secretary of Health and Human Services and the other federal party, respectfully petitions for a writ of certiorari to review the judgment of the United States Court of Appeals for the Seventh Circuit in this case.

OPINIONS BELOW

The opinion of the court of appeals (App., *infra*, 1a-12a) is reported at 143 F.3d 1072. The opinion of the district court (App., *infra*, 13a-21a) is unreported.

JURISDICTION

The judgment of the court of appeals was entered on May 8, 1998. A petition for rehearing was denied on

August 13, 1998. (App., *infra*, 22a-23a). On November 2, 1998, Justice Stevens extended the time within which to file a petition for a writ of certiorari to and including December 12, 1998. On December 4, 1998, Justice Stevens further extended the time within which to file a petition for a writ of certiorari to and including January 10, 1999. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

STATUTORY PROVISIONS INVOLVED

The provisions of 42 U.S.C. 405(g), 405(h), 1395cc(h), and 1395ii are reproduced at App., *infra*, 24a-27a.

STATEMENT

1. In Title XVIII of the Social Security Act, Congress established the federally funded Medicare program to provide health insurance to the elderly and disabled. 42 U.S.C. 1395 *et seq.* Part A of the program provides insurance for covered in-patient hospital and related post-hospital services, including skilled nursing care and related services for residents of qualified skilled nursing facilities. 42 U.S.C. 1395d, 1395i-3, 1395x(j).¹ When patient beneficiaries receive those services, the Secretary reimburses the providers of the services under the Medicare Act and the Secretary's implementing regulations. 42 U.S.C. 1395f(b)(1), 1395x(v)(1)(A).

Skilled nursing facilities must comply with statutory standards for health, safety, and quality of care. 42 U.S.C. 1395i-3(a)-(d); 42 C.F.R. 483.¹ 483.75.² To en-

¹ Part B of Medicare is a voluntary supplementary insurance program covering physician charges and other medical services. 42 U.S.C. 1395k, 1395l, 1395x(s).

² Nursing facilities also must comply with similar standards in order to participate in the Medicaid program. 42 U.S.C. 1396r(a)-(d) (1994 & Supp. II 1996). The Medicaid program, established in

force compliance with those standards, the Act vests the Secretary with authority to impose a broad range of remedies upon a finding of a violation, including direction of a plan for correcting statutory violations, imposition of civil money penalties, denial of further reimbursement for services rendered after the deficiency is discovered, appointment of temporary management, and termination of a facility's right to participate in Medicare. 42 U.S.C. 1395i-3(h)(2); 42 C.F.R. 488.406.

The Act also sets forth comprehensive procedures for administrative and judicial review of enforcement measures taken by the Secretary. If a remedy or sanction is imposed, a nursing facility has a right to an evidentiary hearing before an administrative law judge (ALJ) to contest a finding of a statutory or regulatory violation. 42 C.F.R. 498.3(b)(12), 498.40-498.78.³ The facility may appeal an adverse hearing decision to the Departmental Appeals Board, which may modify, affirm, or reverse the ALJ's decision. 42 C.F.R. 498.80-498.88. Such a decision is the final decision of the Secretary. 42 C.F.R. 498.90(a). A provider may obtain judicial review of the Secretary's final decision after a hearing by filing an action in district court within 60

1965 by Title XIX of the Social Security Act, 42 U.S.C. 1396 *et seq.*, is a cooperative federal-state program to provide medical care to needy individuals.

³ Providers have no right to a hearing, however, if they acquiesce in a finding of deficient care and voluntarily correct the deficiency before a remedy takes effect, or if the provider is subject to the loss of approval for a nurse-aide training program or additional monitoring of the provider's operations. 42 C.F.R. 498.3(b)(12) and (d)(10)(iii). A provider also generally may not challenge an assessment of the violation's scope and severity or the resulting choice of enforcement remedies. 42 C.F.R. 498.3(d)(10)-(11).

days. 42 U.S.C. 1395cc(h)(1) (incorporating 42 U.S.C. 405(g)).⁴ Finally, Section 205(h) of Title II of the Social Security Act, 42 U.S.C. 405(h), made applicable to the Medicare Act by 42 U.S.C. 1395ii, makes those procedures the exclusive means of obtaining judicial review over final decisions of the Secretary:

The findings and decision of the [Secretary] after a hearing shall be binding upon all individuals who were parties to such hearing. No findings of fact or decision of the [Secretary] shall be reviewed by any person, tribunal, or governmental agency except as herein provided. No action against the United States, the [Secretary], or any officer or employee thereof shall be brought under section 1331 or 1346 of title 28 to recover on any claim arising under this subchapter.

42 U.S.C. 405(h).

2. Respondent is a trade association that represents approximately 200 nursing facilities that participate in both the Medicare and the Medicaid programs. App., *infra*, 14a. In May 1996, respondent filed suit in the United States District Court for the Northern District of Illinois seeking injunctive and declaratory relief and invoking the court's jurisdiction under 28 U.S.C. 1331, 1346 (1994 & Supp. II 1996), and 2201. The complaint

⁴ A facility may challenge the imposition of a civil money penalty by filing an action for judicial review in the court of appeals within 60 days. 42 U.S.C. 1395i-3(h)(2)(B)(ii) (incorporating 42 U.S.C. 1320a-7a). Although nursing facilities participating in the Medicaid program (see note 2, *supra*) may obtain an evidentiary hearing to contest a finding of a statutory or regulatory violation, 42 C.F.R. 431.153(i), the Medicaid Act itself does not contain its own provisions for judicial review of an enforcement action taken against a facility. See notes 5 and 11, *infra*.

alleges that the Secretary's regulations governing the enforcement of health and safety standards for nursing facilities are unconstitutionally vague, exceed the Secretary's statutory authority, and deprive facilities of their due process rights by limiting a provider's ability to contest an enforcement action. The complaint also alleges that a manual used by inspectors to survey providers is a substantive rule that must comply with the notice-and-comment rulemaking procedures of the Administrative Procedure Act (APA), 5 U.S.C. 553. See App., *infra*, 13a, 15a.

The district court dismissed the complaint for lack of subject matter jurisdiction. App., *infra*, 13a-21a. The court explained that 42 U.S.C. 405(h) forecloses jurisdiction under 28 U.S.C. 1331 and 1346 (1994 & Supp. II 1996) over the claims asserted on behalf of respondent's Medicare provider members, because those claims arise under the Medicare Act. App., *infra*, 15a-18a. The district court rejected respondent's reliance on this Court's decision in *Bowen v. Michigan Academy of Family Physicians*, 476 U.S. 667 (1986), which held that a federal district court had jurisdiction under Section 1331 to review a challenge to the validity of a Medicare regulation governing payments to physicians under Part B of the Medicare program. At that time, 42 U.S.C. 1395ff (1982) provided for a hearing and judicial review of challenges to the amount of payments made under Part A but not under Part B of the Medicare program. See 476 U.S. at 674 n.5 (quoting 42 U.S.C. 1395ff (1982)); *United States v. Erika, Inc.*, 456 U.S. 201, 207-208 (1982). Relying on the "strong presumption that Congress intends judicial review of administrative action," the Court in *Michigan Academy* concluded that Section 405(h) did not preclude "challenges mounted against the method by which [the]

amounts [of Part B benefits] are to be determined rather than [challenges to] the [amount] determinations themselves." 476 U.S. at 670, 675. Given that statutory framework, the district court concluded that the decision in *Michigan Academy* is premised on the fact that the plaintiffs in that case had "no other avenue of judicial review" to challenge the Secretary's regulations. App., *infra*, 18a.

The district court pointed out that, after this Court's decision in *Michigan Academy*, Congress amended the Medicare Act to provide for administrative and judicial review of challenges to Part B amount determinations. See Pub. L. No. 99-509, § 9341(a)(1), 100 Stat. 2037 (1986) (codified at 42 U.S.C. 1395ff(1)). Thus, because both Part A and Part B participants "now have an avenue of judicial review," the district court concluded that the concern in *Michigan Academy* that agency action would be altogether immune from review "no longer exists." App., *infra*, 18a.

The district court further found that it lacked jurisdiction to consider respondent's claims under 42 U.S.C. 405(g), as incorporated into the Medicare Act for cases such as this by 42 U.S.C. 1395cc(h)(1). The district court explained that Section 405(g) imposes two requirements for obtaining judicial review: a non-waivable requirement of presentment of the claim to the Secretary and a waivable requirement of exhaustion of administrative remedies. App., *infra*, 18a-19a. The district court concluded that because respondent "has not alleged or shown any attempt at presentment of [its] claims to the Secretary," the court lacks subject

matter jurisdiction over the claims arising under the Medicare Act. *Id.* at 19a.⁵

3. The court of appeals vacated and remanded for further proceedings. App., *infra*, 1a-12a. The court of appeals observed that this Court's decisions in *Heckler v. Ringer*, 466 U.S. 602 (1984), and *Weinberger v. Salfi*, 422 U.S. 749 (1975), "treat th[e] language [of 42 U.S.C. 405(h)] as channeling all claims to benefits through the administrative forum, no matter what legal theory underlies the claim." App., *infra*, 4a. Relying on *Michigan Academy*, however, the court of appeals concluded that Section 405(h) precludes a provider's challenge relating to a "request for reimbursement" but permits an "anticipatory challenge to implementing regulations." *Id.* at 4a, 5a. The court of appeals reasoned that, even though "[i]t may well be that the 1986 amendments [to Part B] remove the practical support for the distinction drawn by *Michigan Academy*" between "pre-enforcement challenges to Medicare regulations * * * and requests for reimbursement," "[u]ntil the Supreme Court tells us that it believes that the 1986 amendments require a change of direction

⁵ The district court dismissed respondent's claims brought under the Medicaid program. App., *infra*, 19a-20a. The court reasoned that "[b]y reaching the merits on the Medicaid claims, this court would effectively resolve the Medicare issues as well. This attempt to back-door the jurisdictional bar of the Medicare Act is impermissible." *Ibid.* In the court of appeals, the Secretary acknowledged that, because the Medicaid Act does not contain provisions comparable to 42 U.S.C. 405(g) and (h), see note 4, *supra*, the district court had subject matter jurisdiction under 28 U.S.C. 1331 over the claims brought on behalf of respondent's members participating *solely* in the Medicaid program, to the extent those claims were otherwise justiciable. App., *infra*, 2a-3a; Gov't C.A. Br. 15-16, 28-29. Seventy-five of respondents' members participate only in the Medicaid program. Amended Compl. ¶ 6.

* * *, we are obliged to follow the holding of *Michigan Academy*." *Id.* at 5a, 7a.⁶

The Secretary filed a petition for rehearing and suggestion of rehearing en banc. The court of appeals denied the petition, although three judges voted to grant rehearing en banc. App., *infra*, 22a-23a & n.2.

REASONS FOR GRANTING THE PETITION

This case presents two questions at issue in *Your Home Visiting Nurse Services, Inc. v. Shalala*, No. 97-1489 (argued Dec. 2, 1998). Both this case and *Your Home* concern whether the preclusive language of Section 405(h) bars an action to review agency action under the Medicare program where subject matter jurisdiction is based on 28 U.S.C. 1331. Both cases also concern whether this Court's decision in *Bowen v. Michigan Academy of Family Physicians*, 476 U.S. 667 (1986), has continuing application when the Medicare Act itself affords a provider with an opportunity to obtain administrative and judicial review over agency action. As we note in our merits brief in *Your Home*, Gov't Br. 40-41 n.18, the court of appeals' decision in this case conflicts with the great weight of appellate authority. Because the Court's resolution in *Your Home* may govern the disposition of this case, the

⁶ The court of appeals dismissed as unripe respondent's vagueness challenge to the Secretary's regulations. App., *infra*, 10a-11a. The court of appeals observed that, "[i]n order to take advantage of *Michigan Academy*, [respondent] made its claim entirely abstract," by "not object[ing] to any evaluation of any particular nursing home or contend[ing] that a single one of its members has been ill used." *Id.* at 9a. The court of appeals also remanded to the district court respondent's due process and statutory claims for a determination whether those claims were justiciable, and further remanded respondent's APA notice-and-comment claim for consideration on the merits. *Id.* at 11a-12a.

petition in this case should be held pending the decision in *Your Home* and then disposed of in light of that decision.⁷

1. a. The principal question presented in *Your Home* is whether a fiscal intermediary's refusal to reopen a provider's annual reimbursement determination is subject to review by the Provider Reimbursement Review Board (PRRB) under 42 U.S.C. 1395oo(a), which in turn would result in a right to judicial review of the PRRB's final decision under 42 U.S.C. 1395oo(f). If the Court concludes in *Your Home* that the provider is not entitled to such administrative review, however, the Court will consider the *Your Home* petitioner's alternative contention that this Court's decision in *Michigan Academy* permits a federal district court, exercising jurisdiction under 28 U.S.C. 1331, to review (presumably pursuant to the APA) an intermediary's refusal to reopen a prior reimbursement determination. Pet. Br. 18-23.⁸ The Secretary has argued in *Your Home* (Gov't Br. 36-42) that such jurisdiction is specifically precluded by the second and third sentences of Section 405(h), incorporated into the Medicare Act by 42 U.S.C. 1395ii, which provide that:

No findings of fact or decision of the [Secretary] shall be reviewed by any person, tribunal, or governmental agency except as herein provided. No action against the United States, the [Secretary], or

⁷ We are providing counsel for respondent with a copy of our brief filed in *Your Home*.

⁸ The petitioner in *Your Home* also contends that a federal court has subject matter jurisdiction under 28 U.S.C. 1361 and 5 U.S.C. 706 to review an intermediary's denial of a provider's reopening request. Pet. Br. 24-40. Those asserted bases for jurisdiction are not involved in this case.

any officer or employee thereof shall be brought under section 1331 * * * of title 28 to recover on any claim arising under this subchapter.

42 U.S.C. 405(h). Section 405(h) equally bars respondent's suit in this case.

This Court has made clear that the preclusive language of Section 405(h) is "sweeping and direct and * * * states that *no action shall be brought under § 1331.*" *Weinberger v. Salfi*, 422 U.S. 749, 757 (1975). Similarly, in *Heckler v. Ringer*, 466 U.S. 602 (1984), the Court held that "[t]he third sentence of 42 U.S.C. § 405(h) * * * provides that [42 U.S.C.] 405(g), to the exclusion of 28 U.S.C. § 1331, is the sole avenue for judicial review for all 'claim[s] arising under' the Medicare Act." *Id.* at 614-615 (quoting 42 U.S.C. 405(h)). The Court in *Ringer* explained that Section 405(h) "broadly" extends to "any claims in which 'both the standing and the substantive basis for the presentation' of the claims" is the Medicare Act. 466 U.S. at 615 (quoting *Salfi*, 422 U.S. at 761). The Court therefore concluded that all such claims must be brought under Section 405(g) by presenting the claims to the Secretary and exhausting administrative remedies, absent a waiver by the Secretary. 466 U.S. at 617; see also *Bowen v. City of New York*, 476 U.S. 467, 482-483 (1986); *Mathews v. Eldridge*, 424 U.S. 319, 327-328 (1976); *Salfi*, 422 U.S. at 763-767.⁹

⁹ As this Court observed in *Salfi*, 422 U.S. at 765, "the purpose of requiring claimants to exhaust administrative remedies is to 'prevent[] premature interference with agency processes, so that the agency may function efficiently and so that it may have an opportunity to correct its own errors, to afford the parties and the courts the benefit of its experience and expertise, and to compile a record which is adequate for judicial review.'"

Those principles foreclose jurisdiction under 28 U.S.C. 1331 and 1346 (1994 & Supp. II 1996) over respondent's claims for declaratory relief.¹⁰ Respondent seeks review of the validity of the Secretary's regulations that implement the statutory health and safety standards for nursing facilities participating in the Medicare program. The district court correctly concluded that, because respondent's claims asserted on behalf of Medicare providers arise under the Medicare Act, App., *infra*, 15a-18a, Section 405(h) bars a district court from exercising jurisdiction under Sections 1331 and 1346 to hear those claims.¹¹ Moreover, because respondent neither presented its claims to the Secretary nor exhausted its administrative remedies, the district court correctly concluded that it lacked jurisdiction under Section 405(g) to hear such claims.¹²

¹⁰ Although respondent also asserts that the Declaratory Judgment Act, 28 U.S.C. 2201, furnishes an alternative basis for the district court's subject matter jurisdiction (Amended Compl. ¶ 11), that provision is not an independent grant of jurisdiction. *Skelly Oil Co. v. Phillips Petroleum Co.*, 339 U.S. 667, 671-672 (1950).

¹¹ Sections 405(g) and 405(h) also foreclose the challenges brought by a provider that participates in *both* the Medicare and Medicaid programs because such claims also arise under the Medicare Act. Those providers are governed by essentially identical standards, 42 U.S.C. 1395i-3(a)-(d) and (g) (Medicare); 42 U.S.C. 1396r(a)-(d) and (g) (1994 & Supp. II 1996) (Medicaid), and dually participating providers are required to employ the administrative remedies set forth for the Medicare program. 42 C.F.R. 431.153(g). A contrary conclusion would circumvent Congress's intent in Sections 405(g) and 405(h) to require exhaustion of administrative remedies over claims arising under the Medicare Act. Cf. note 9, *supra*.

¹² The APA reinforces the exclusivity mandated by Sections 405(g) and 405(h). The APA expressly provides that "[t]he form of

In reaching the contrary conclusion, the court of appeals reasoned that “pre-enforcement review of a regulation’s validity is not an action to ‘recover on’ a claim” within the meaning of Section 405(h). App., *infra*, 6a. This Court in *Ringer*, however, rejected as “superficially appealing but ultimately unavailing” the contention that Section 405(h) excepts from its breadth a challenge to a regulation that is divorced from a specific claim for benefits. 466 U.S. at 621. Rather, the Court found that federal courts lack jurisdiction under 28 U.S.C. 1331 to award declaratory and injunctive relief respecting the Secretary’s policy not to cover a particular surgical procedure, even if a claimant has not undergone the surgery and therefore has no concrete claim for reimbursement on which he could recover. *Id.* at 621-626; compare *id.* at 631 n.9 (Stevens, J., concurring in part and dissenting in part) (arguing that such a claimant had “nothing on which he can recover” when he had not yet submitted a reimbursement claim). In short, the Court concluded that “[i]n the best-of all worlds, immediate judicial access * * * might be desirable. But Congress, in § 405(g), and § 405(h), struck a different balance, refusing declaratory relief and requiring that administrative remedies be exhausted before judicial review of the Secretary’s decisions takes place.” *Id.* at 627. Thus, the court of appeals’ decision conflicts with this Court’s decision in

proceeding for judicial review is the special statutory review proceeding relevant to the subject matter,” 5 U.S.C. 703, and permits a district court action only if “there is no other adequate remedy in a court.” 5 U.S.C. 704. Because Section 405(g) furnishes respondent and its Medicare-provider members a fully adequate remedy for challenges to enforcement actions and standards, review directly in the district court under the APA would not be available in any event.

Ringer, which construed the plain text of Section 405(h) to preclude “all ‘claim[s] arising under’ the Medicare Act,” 466 U.S. at 615 (quoting 42 U.S.C. 405(h)).

b. The court of appeals also erred in relying on this Court’s decision in *Michigan Academy* to permit respondent to bypass the Medicare Act’s specific administrative and judicial remedies. In *Michigan Academy*, the Court permitted plaintiffs to invoke the district court’s jurisdiction under Section 1331 to challenge the validity of reimbursement regulations under Part B of the Medicare program at a time when 42 U.S.C. 1395ff (1982) provided for a hearing and judicial review of challenges to the amount of payments made under Part A but not Part B of the program. 476 U.S. at 674 n.5 (quoting 42 U.S.C. 1395ff (1982)); *United States v. Erika, Inc.*, 456 U.S. 201, 207-208 (1982). Rejecting what it termed the “extreme” position taken by the government that Congress intended Section 405(h) to foreclose “all” judicial review of facial challenges to the Secretary’s regulations, the Court held that Section 405(h) did not preclude “challenges mounted against the method by which [the] amounts [of Part B benefits] are to be determined.” 476 U.S. at 675, 680.

Michigan Academy does not support jurisdiction over respondent’s claims outside the specific review provisions of the Medicare Act. Unlike the situation in *Michigan Academy*, in which jurisdiction under Section 1331 was the sole jurisdictional basis for obtaining judicial review of administrative action under Part B of the program as it then existed, Section 405(g), as incorporated into the Medicare Act by 42 U.S.C. 1395cc(h)(1), explicitly affords respondent an avenue to challenge the Secretary’s regulations. Thus, Section 405(g) expressly confirms the district court’s power to “review * * * the validity of [the Secretary’s]

regulations" when it reviews the Secretary's final decision. Because judicial review of regulations is available, the presumption of judicial review underlying the decision in *Michigan Academy* is not "implicate[d]." *Thunder Basin Coal Co. v. Reich*, 510 U.S. 200, 207 n.8 (1994); see also *McNary v. Haitian Refugee Ctr., Inc.*, 498 U.S. 479, 498 (1991) ("Inherent in our analysis [in *Michigan Academy*] was the concern that absent such a construction of the * * * statute, there would be 'no review at all of substantial statutory and constitutional challenges to the Secretary's administration of Part B of the Medicare program.'") (quoting *Michigan Academy*, 476 U.S. at 680). Accordingly, under Section 405(h) and this Court's decisions in *Ringer* and *Salfi*, the Medicare Act is the sole means of obtaining judicial review over claims arising under the Act.

2. In holding that Medicare providers may bring a pre-enforcement APA challenge to the Secretary's regulations by invoking the district court's jurisdiction under 28 U.S.C. 1331, the court of appeal's decision departs from the great weight of appellate authority.

In *Michigan Ass'n of Homes & Services for the Aging, Inc. v. Shalala*, 127 F.3d 496 (1997), the Sixth Circuit rejected the attempt by an association of nursing facilities to invoke a district court's jurisdiction under Section 1331 to raise claims that are virtually identical to those asserted by respondent. *Id.* at 498-499. The Sixth Circuit held that under the express terms of Section 405(h), and this Court's decisions in *Ringer* and *Salfi*, judicial review under Section 405(g) is the sole means to challenge the Secretary's regulations, and providers therefore may not invoke the jurisdiction of a district court under Section 1331 to circumvent Section 405(g)'s requirements of presentment to the Secretary and exhaustion of administrative remedies.

Id. at 499-501. The Sixth Circuit further held that *Michigan Academy* did not support the assertion of federal question jurisdiction. The court reasoned that "[a]dministrative review—and so long as * * * sections 405(g) and (h) are fulfilled, judicial review—is available any time a sanction is actually imposed." *Id.* at 501.

The Sixth Circuit's decision therefore squarely conflicts with the court of appeals' decision in this case. The court of appeals' decision similarly is inconsistent with the Third Circuit's decision in *St. Francis Medical Center v. Shalala*, 32 F.3d 805, 812-813 (1994), cert. denied, 514 U.S. 1016 (1995), which holds that the administrative and judicial review provisions of the Medicare Act are the sole means of obtaining review of provider reimbursement claims arising under Part A of the Medicare program. See also *Westchester Management Corp. v. HHS*, 948 F.2d 279, 282 (6th Cir. 1991) (court lacked jurisdiction under Sections 1331 and 1346 to consider provider's APA, statutory, and constitutional challenge to Medicare regulation), cert. denied, 504 U.S. 909 (1992).

Moreover, the court of appeals' decision conflicts with the decisions of those courts of appeals that have applied *Michigan Academy* in light of subsequent legislative changes to Part B of the Medicare program. As the Seventh Circuit recognized in this case (App., *infra*, 4a-6a), Congress amended 42 U.S.C. 1395ff in 1986 to provide for administrative and judicial review of challenges to carrier determinations concerning the amount of payments made under Part B of the program. Pub. L. No. 99-509, § 9341(a)(1), 100 Stat. 2037. In light of that amendment, the courts of appeals have held that Part B claimants must pursue the specific review procedures under Section 405(g), and that Section 405(h)

bars federal courts from exercising jurisdiction under 28 U.S.C. 1331 to review claims arising under Part B of the Medicare program, including the type of facial challenges to regulations at issue in *Michigan Academy*. See *American Academy of Dermatology v. HHS*, 118 F.3d 1495, 1497-1501 (11th Cir. 1997); *Farkas v. Blue Cross & Blue Shield*, 24 F.3d 853, 855-860 (6th Cir. 1994); *Abbey v. Sullivan*, 978 F.2d 37, 41-44 (2d Cir. 1992); *National Kidney Patients Ass'n v. Sullivan*, 958 F.2d 1127, 1130-1134 (D.C. Cir. 1992), cert. denied, 506 U.S. 1049 (1993).¹³ Thus, disregarding the express terms of Section 405(h), the court of appeals' decision in this case conflicts with the substantial body of appellate authority that has held that Medicare providers may not invoke the jurisdiction of a federal district court under Section 1331 to circumvent the administrative and judicial review procedures prescribed by the Medicare Act.

CONCLUSION

The petition for a writ of certiorari should be held pending the decision in *Your Home Visiting Nurse Services, Inc. v. Shalala*, No. 97-1489 (argued Dec. 2, 1998), and then disposed of as appropriate in light of the decision in that case.

Respectfully submitted.

SETH P. WAXMAN
Solicitor General

JANUARY 1999

¹³ Indeed, the Seventh Circuit itself has acknowledged that, because "the *Michigan Academy* distinctions drawn between 'amount of payment' and 'validity of the statute and regulations' challenges are no longer meaningful or necessary," the review provisions of Section 405(g) "now provide the full authority for exercising jurisdiction over Part A and Part B disputes." *Martin v. Shalala*, 63 F.3d 497, 503 (1995).

APPENDIX A

**UNITED STATES COURT OF APPEALS
FOR THE SEVENTH CIRCUIT**

No. 97-2315

**ILLINOIS COUNCIL ON LONG TERM CARE INC.,
PLAINTIFF-APPELLANT**

v.

**DONNA E. SHALALA, SECRETARY OF HEALTH AND
HUMAN SERVICES, ET AL., DEFENDANTS-APPELLEES**

[Argued: Dec. 5, 1997
Decided: May 8, 1998]

Before: EASTERBROOK, DIANE P. WOOD, and EVANS,
Circuit Judges

EASTERBROOK, Circuit Judge.

Nursing homes that want reimbursement under the Medicare or Medicaid programs must comply with regulations specifying minimum health and safety standards. Statutory criteria were enacted in 1987, see 42 U.S.C. § 1395i-3(a) to (d) (Medicare), § 1396r(a) to (d) (Medicaid), but implementing regulations were not issued until 1994, and did not take effect until July 1, 1995. 59 Fed.Reg. 56,116 (1994). An association of nursing homes, the Illinois Council on Long Term Care,

(1a)

tells us that before these new regulations were adopted about 6% of its members had been directed to change their operations in order to meet applicable standards, while more recent inspections have found 70% of nursing homes to be deficient. Regulators attribute this to tougher substantive rules that nursing homes have yet to satisfy; the nursing homes attribute the jump to vague rules that leave too much discretion in the hands of inspection teams.

The Council filed this suit on behalf of its members and asked the court to declare that the new regulations violate the due process clause of the fifth amendment because they are too vague and do not provide adequate opportunities to be heard before financial penalties take effect. The Council also argued that a manual used by inspection teams has the effect of a regulation and therefore could be adopted only after notice-and-comment rulemaking under § 3 of the Administrative Procedure Act, 5 U.S.C. § 553. The Secretary of Health and Human Services, the principal defendant in the case, asked the district court to distinguish between the Medicare and Medicaid aspects of the suit. According to the Secretary, objections to implementation of the Medicare Act are barred by 42 U.S.C. § 1395ii, incorporating 42 U.S.C. § 405(h), which makes an application for benefits (and review of the Secretary's final decision), the sole route to judicial review. None of the Council's members has obtained a final decision, and § 1395ii forbids jumping the gun on legal issues that will be relevant to the administrative decision, the Secretary contended. *See Heckler v. Ringer*, 466 U.S. 602, 104 S. Ct. 2013, 80 L.Ed.2d 622 (1984). Although most of the Council's theories are based on the Constitution and the APA rather than any incompatibility between

the regulations and the Medicare Act, *Weinberger v. Salfi*, 422 U.S. 749, 95 S. Ct. 2457, 45 L.Ed.2d 522 (1975), holds that a claim is subject to the review-channeling provision in § 405(h) when the end in view is receipt of federal payments. Claims under the Medicaid Act should be handled otherwise, the Secretary submitted, because that statute does not incorporate § 405(h) and lacks any comparable restriction. A challenge to Medicaid regulations therefore is proper under 28 U.S.C. § 1331 and 5 U.S.C. § 702—but, the Secretary added, should be dismissed in large measure as unripe. Only the Medicaid providers' APA challenge to the handbook is mete for decision, the Secretary concluded. The district judge accepted the first part of this argument—that § 1395ii postpones review of claims by Medicare providers—but extended it to the entire case, stating: “The issues are the same, the only difference being that the first three counts arise under the Medicaid Act whereas the latter three arise under the Medicare Act. By reaching the merits on the Medicaid claims, this court would effectively resolve the Medicare issues as well. This attempt to back-door the jurisdictional bar of the Medicare Act is impermissible.” 1997 WL 158347 at *3, 1997 U.S. Dist. Lexis 3982 at *9-10. After the Council filed its notice of appeal, the sixth circuit reached the same conclusion in an essentially identical case. *Michigan Association of Homes & Services for the Aging, Inc. v. Shalala*, 127 F.3d 496 (6th Cir.1997).

Section 1395ii makes § 405(h) applicable to Medicare cases “to the same extent as” it applies to Social Security disability cases. Section 405(h) provides in part: “No findings of fact or decision of the [Secretary] shall be reviewed by any person, tribunal, or governmental

agency except as herein provided. No action against the United States, the [Secretary], or any officer or employee thereof shall be brought under § 1331 or 1346 of Title 28 to recover on any claim arising under this subchapter." The word "herein" refers to the rest of § 405, and in particular to § 405(g), which permits judicial review only after a final decision by the Secretary. *Ringer* and *Salfi* treat this language as channeling all claims to benefits through the administrative forum, no matter what legal theory underlies the claim. But *Bowen v. Michigan Academy of Family Physicians*, 476 U.S. 667, 678-81, 106 S. Ct. 2133, 2140-41, 90 L.Ed.2d 623 (1986), holds that § 1395ii does not foreclose Medicare providers' anticipatory challenge to implementing regulations. Bypassing the question whether § 405(h) would prevent such a challenge to a regulation implementing the Social Security disability program, the Court held that § 1395ii addresses only "amount determinations" (476 U.S. at 680, 106 S. Ct. at 2141)—that is, calculations of reimbursements by the fiscal intermediaries that implement the Medicare program—and that "matters which Congress did *not* delegate to private carriers, such as challenges to the validity of the Secretary's instructions and regulations, are cognizable in courts of law." *Ibid.* (emphasis in original).

According to the Secretary, *Michigan Academy* ceased to have any precedential force a few months after it was issued. The Secretary reads *Michigan Academy* as creating an exception to § 1395ii for claims that otherwise could not reach the courts. Shortly after the Court decided *Michigan Academy*, Congress amended the Medicare Act to give providers an avenue to judicial review of amount determinations, 42 U.S.C.

§ 1395ff(b)(1), thus overturning the result of *United States v. Erika, Inc.*, 456 U.S. 201, 102 S. Ct. 1650, 72 L.Ed.2d 12 (1982). Once that occurred, the argument concludes, the basis of *Michigan Academy* disappeared, and with it the Court's holding. The district court, and the sixth circuit in *Michigan Association*, 127 F.3d at 500-01, accepted this line of argument. But if something important happened in 1986, the point has been lost on the Supreme Court, which in 1991 reiterated its conclusion that § 1395ii does not affect regulatory challenges that are detached from any request for reimbursement. *McNary v. Haitian Refugee Center, Inc.*, 498 U.S. 479, 497-98, 111 S. Ct. 888, 898-99, 112 L.Ed.2d 1005 (1991). And it has been lost on us too, for we have since 1986 drawn a distinction between pre-enforcement challenges to Medicare regulations (allowed) and requests for reimbursement (postponed until after the Secretary has made a final decision). *E.g., Martin v. Shalala*, 63 F.3d 497, 503-05 (7th Cir.1995); *Bodimetric Health Services, Inc. v. Aetna Life & Casualty*, 903 F.2d 480, 483-87 (7th Cir.1990).

It may well be that the 1986 amendments remove the practical support for the distinction drawn by *Michigan Academy*. The panel in *Martin* said as much. 63 F.3d at 502-03. *Michigan Academy* emphasized, 476 U.S. at 670-73, 106 S. Ct. at 2135-37, the presumption that Congress has allowed some avenue of judicial review, and the Justices read the statutes then in effect with that presumption in mind. Now that Congress has authorized review of amount determinations through § 1395ff(b)(1), that part of *Michigan Academy*'s rationale is gone—the invalidity of regulations would be a good reason for a reviewing court to upset an amount determination. This led the district court to write that

"the *Michigan Academy* exception does not apply." Both the Secretary and the district court thus treat the Supreme Court's opinion as an "exception" to a statute—as if the Court claimed the power to treat statutes no differently from the common law, and to make "exceptions" to Acts of Congress based on judicially created presumptions. Cf. Guido Calabresi, *A Common Law for the Age of Statutes* (1982). To the contrary, the Court has disavowed such power. E.g., *Bank of Nova Scotia v. United States*, 487 U.S. 250, 255, 108 S. Ct. 2369, 2373-74, 101 L.Ed.2d 228 (1988). *Michigan Academy* does not say that a presumption of judicial review justifies an "exception" to § 1395ii. It says, rather, that § 1395ii, read in light of its 1972 legislative history, affects only "amount determinations". 476 U.S. at 678-81, 106 S. Ct. at 2140-41. The key language from this perspective is "recover on" in the sentence: "No action against the United States, the [Secretary], or any officer or employee thereof shall be brought under § 1331 or [§] 1346 . . . to recover on any claim arising under this subchapter." As the Court read § 1395ii and therefore § 405(h) in *Michigan Academy*, pre-enforcement review of a regulation's validity is not an action to "recover on" a claim, even when per *Salfi* a constitutional objection to the regulation is a "claim arising under this subchapter."

Neither this critical language from § 405(h) nor the history of § 1395ii changed in 1986. Had Congress written a new statute, we would need to decide what the new language means, rather than what *Michigan Academy* said some bygone language meant. But when Congress amended § 1395ff it left § 1395ii alone. Section 1395ii was amended in 1994 (see § 108(c)(4) of Pub.L. 103-296, 108 Stat. 1485), but that change was

designed only to make it clear that a bureaucratic reorganization (the removal of the Commissioner of Social Security from the Department of Health and Human Services) had no substantive effects. The operative language is the same now as it was when *Michigan Academy* came down. The Supreme Court is jealous of its powers and insists that the inferior courts are not authorized to declare the reasoning of its opinions outdated and their holdings passe. See *State Oil Co. v. Khan*, — U.S. —, 118 S. Ct. 275, 284, 139 L.Ed.2d 199 (1997); *Rodriguez de Quijas v. Shearson/American Express, Inc.*, 490 U.S. 477, 484, 109 S. Ct. 1917, 1921-22, 104 L.Ed.2d 526 (1989); *Thurston Motor Lines, Inc. v. Jordan K. Rand, Ltd.*, 460 U.S. 533, 535, 103 S. Ct. 1343, 1344, 75 L.Ed.2d 260 (1983). Until the Supreme Court tells us that it believes that the 1986 amendments require a change of direction with respect to § 1395ii, we are obliged to follow the holding of *Michigan Academy*.

Although this conclusion makes it unnecessary to discuss in detail the distinctions between the Medicare and Medicaid programs, the possibility that this case may find its way to a higher tribunal leads us to record our disagreement with the district court's conclusion that challenges to Medicaid regulations are barred whenever the decision has implications for Medicare regulations. The Medicaid Act contains nothing comparable to § 405(h) or § 1395ii. The general federal-question jurisdiction under § 1331 therefore supplies the avenue of judicial review, and it has been understood for a long time that courts are not to invent novel obstacles to the use of this jurisdiction. See *Colorado River Water Conservation District v. United States*, 424 U.S. 800, 817, 96 S. Ct. 1236, 1246, 47 L.Ed.2d 483

(1976). We have entertained challenges to Medicaid regulations without hinting that a district court should dismiss the case (effectively abstaining) if a similar problem could arise under the Medicare Act or its regulations. See *Woodstock/Kenosha Health Center v. Schweiker*, 713 F.2d 285, 288-89 (7th Cir.1983); *Illinois Department of Public Aid v. Schweiker*, 707 F.2d 273 (7th Cir.1983). The district court did not mention these cases; instead it relied on an earlier decision, *Rhode Island Hospital v. Califano*, 585 F.2d 1153, 1162-63 (1st Cir.1978), that is incompatible with the law of this circuit. The Medicare and Medicaid programs have many substantive and procedural differences; it is not as if they were twins, so that a court should struggle to avert the possibility of allowing judicial review at different times or through different mechanisms. Nursing homes that participate in the Medicaid program are not limited to the Medicare procedures. If some nursing homes may litigate on their own, they may litigate through their trade association; we don't see why the fact that other members of the Council have potential Medicare claims should cut off associational representation and compel independent litigation.

Thus we disapprove the sixth circuit's decision in *Michigan Association* across the board, for it is inconsistent with *Woodstock/Kenosha*, and similar cases in this circuit, none of which the sixth circuit cited. *Michigan Association* claimed to follow *Health Equity Resources Urbana, Inc. v. Sullivan*, 927 F.2d 963 (7th Cir.1991), which it read for the proposition that the Medicaid Act's incorporation of 42 U.S.C. § 405(g) via 42 U.S.C. § 1396i(b)(2) is independently sufficient to prevent anticipatory judicial review of regulations. Any interpretative exercise that makes multiple

sections of the United States Code meaningless—and this one would dispense with at least § 405(h) and § 1395ii—and requires a federal court to renounce its own jurisdiction into the bargain, is more than a little suspect. It is not at all what our opinion in *Health Equity Resources* was about. That Medicaid provider commenced an administrative proceeding under § 405(g) and § 1396i(c)(2) to contest an "amount determination" by a fiscal intermediary. Dissatisfied with how things were going, the provider attempted to initiate a suit before the administrative proceeding was over. Applying standard doctrines of exhaustion of administrative remedies, *Health Equity Resources* nixed the maneuver. We did not hold then, and decline to hold now, that a Medicaid provider is forbidden to bring a pre-enforcement challenge to a Medicaid regulation under § 1331.

It follows from what we have said so far that the district court should have resolved on the merits the Council's argument that the manual is a regulation for which notice-and-comment rulemaking was essential. For the most part, however, the Council's victory on the jurisdictional issue does it little good. In order to take advantage of *Michigan Academy*, the Council made its claim entirely abstract. It does not object to any evaluation of any particular nursing home or contend that a single one of its members has been ill used. Such arguments would have played into the Secretary's hands by making it easier to contend that this is just a disguised effort to contest "amount determinations" and therefore postponed (by § 1395ii and *Ringer*) until after the administrative process has run its course. But by making the claim so abstract, the

Council set up the Secretary's contention that the suit is unripe.

One aspect of the Council's attack is assuredly premature. The nursing homes contend that the regulations are void for vagueness. But this is not a first amendment case. It is about conditions attached to a federal subsidy; none of any nursing home's substantive constitutional rights is in jeopardy. That makes it impossible to mount a "facial" attack on the rules. If a rule "implicates no constitutionally protected conduct, [the court] should uphold the challenge only if the enactment is impermissibly vague in all of its applications. A plaintiff who engages in some conduct that is clearly proscribed cannot complain of the vagueness of the law as applied to the conduct of others. A court should therefore examine the complainant's conduct before analyzing other hypothetical applications of the law." *Hoffman Estates v. The Flipside, Hoffman Estates, Inc.*, 455 U.S. 489, 494-95, 102 S. Ct. 1186, 1191, 71 L.Ed.2d 362 (1982) (footnote omitted). In other words, "vagueness challenges . . . which do not involve First Amendment freedoms must be examined in the light of the facts of the case at hand." *United States v. Mazurie*, 419 U.S. 544, 550, 95 S. Ct. 710, 714, 42 L.Ed.2d 706 (1975). Having crafted a litigation strategy to avoid § 405(h) and § 1395ii, the Council finds itself with no "facts of the case at hand" and therefore without any hope of success on a claim that the regulations are unconstitutional vagueness. It is indeed hard to see how regulations under a social welfare program could be condemned out of hand as Delphian. Agencies may use ambiguous standards that acquire meaning through the process of application, just as the common law does. See, e.g., *Parker v. Levy*, 417 U.S. 733, 94 S. Ct. 2547, 41

L.Ed.2d 439 (1974); *NLRB v. Bell Aerospace Co.*, 416 U.S. 267, 294, 94 S. Ct. 1757, 1771-72, 40 L.Ed.2d 134 (1974); *CSC v. Letter Carriers*, 413 U.S. 548, 93 S. Ct. 2880, 37 L.Ed.2d 796 (1973). An industry subject to a battery of new regulations cannot ask for an all-at-once review but must wait until the agency has worked through the process of adding detail in administrative adjudication. See *Machinists Union v. NLRB*, 133 F.3d 1012, 1015-17 (7th Cir.1998).

To the extent the Council complains that the manual and accompanying survey forms are unauthorized by the 1987 legislation, these claims may be mooted by a decision on the APA theory. Other aspects of this line of argument may be inappropriate for pre-enforcement review given the standards of *Babbitt v. United Farm Workers*, 442 U.S. 289, 298-99, 99 S. Ct. 2301, 2308-09, 60 L.Ed.2d 895 (1979); *Gardner v. Toilet Goods Association*, 387 U.S. 167, 87 S. Ct. 1526, 18 L.Ed.2d 704 (1967); and *Abbott Laboratories v. Gardner*, 387 U.S. 136, 87 S. Ct. 1507, 18 L.Ed.2d 681 (1967). For example, the Council insists that the regulations and manual will not assure that remedies are consistently applied to similarly situated nursing homes, which 42 U.S.C. § 1395i-3(g)(2)(D) requires the Secretary to do. But how could a court determine, without examining how the system works in practice, whether remedies have been applied consistently? Some other arguments based on the 1987 statute do not appear to present situations in which lack of pre-enforcement review will put the plaintiffs to costly choices—and if anticipatory review is not essential to avoid hardship, then courts should defer review, in order to obtain the benefits of the more focused presentation made possible by a concrete application of the rules. See *Texas v. United*

States, — U.S. —, 118 S. Ct. 1257, 140 L.Ed.2d 406 (1998).

Finally, to the extent the Council believes that the regulations fail to provide pre-deprivation hearings at the times (and in the form) the Constitution demands, the claim may be ripe for decision. But because the appellate papers leave us unsure just what this claim entails and how it affects any particular nursing home, it is best to leave to the district court the resolution of the Secretary's ripeness objection to this aspect of the Council's suit.

In sum: the APA-based objection to adoption of the manual is within the district court's jurisdiction and should be addressed on the merits; the vagueness challenge is not ripe for decision and should be dismissed; the due process objection to the timing and structure of opportunities to be heard, and the arguments based on the 1987 statute, may or may not be ripe for decision, and the district court should require the parties to flesh out these claims before deciding which, if any, is justiciable. The judgment is vacated, and the case is remanded for further proceedings consistent with this opinion.

APPENDIX B**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS**

No. 96 C 2953

ILLINOIS COUNCIL FOR LONG TERM CARE, INC.,
PLAINTIFF,

vs.

DONNA E. SHALALA, ET AL., DEFENDANTS

[March 31, 1997]

MEMORANDUM AND ORDER

LINDBERG, District Judge.

Plaintiff, Illinois Council for Long Term Care, has filed a complaint requesting injunctive and declaratory relief against defendants, Secretary Donna Shalala of the Department of Health and Human Services; Anthony J. Tirone, in his capacity as Deputy Director of the United States Office of Survey and Certification, Health Standards and Quality Bureau, Health Care Financing Administration; and John R. Lumpkin, M.D., as Director of the Illinois Department of Public Health (IDPH). Defendants have moved to dismiss all claims pursuant to Fed.R.Civ.P. 12(b)(1) and 12(b)(6).

Plaintiff represents approximately two-hundred nursing homes. Approximately 75 of these members participate only in Medicare. The remaining members participate in either Medicaid or both Medicare and Medicaid. Plaintiff's case arises from the following facts.

The Department of Health and Human Services (HHS) has given the Health Care Financing Administration (HCFA) the responsibility to establish a set of requirements of participation. 42 C.F.R. § 483.1(b). A nursing home must be in compliance with these requirements in order to receive Medicare and Medicaid reimbursements for its patients. In Illinois, the IDPH conducts annual surveys of nursing homes in order to determine whether they are in substantial compliance.

HCFA has developed regulations and distributed Standard Operating Manuals to state agencies such as the IDPH. The IDPH uses them as a guide for surveys and imposing penalties when a nursing home is found to be in non-compliance. In 1987, the Congress amended the Social Security Act with the Omnibus Budget Reconciliation Act (OBRA) in an attempt to improve upon the health, safety, and rights of participants. The amendments called for stricter guidelines and more severe penalties. The first set of HCFA's regulations used the pre-1987 OBRA amendments as its enforcement guidelines. Under these regulations, only 6% of nursing homes in Illinois were found to be in non-compliance. In 1995, HCFA's new set of regulations went into effect. These regulations took into account the 1987 OBRA amendments. Nearly 70% of nursing homes in Illinois were found to be in non-compliance under these new regulations.

Plaintiff claims that this drastic change in the rate of non-compliance is because the new regulations and Standard Operating Manuals are unconstitutionally vague, that the new regulations and Standard Operating Manuals were enacted in violation of the Administrative Procedure Act, and that the lack of a sufficient appeals process is a violation of due process.

Defendants, pursuant to Fed. R. Civ. P. 12(b)(1), move to dismiss for lack of subject matter jurisdiction. "The general rule . . . is that absent clear direction to the contrary by Congress, the federal courts have the power to award any appropriate relief in a cognizable cause of action brought pursuant to a federal statute." *Franklin v. Guinnett County Public Schools*, 503 U.S. 60, 70-71, 112 S. Ct. 1028, 117 L.Ed.2d 208 (1992). This jurisdictional issue must be resolved first.

Plaintiff contends that this court has subject matter jurisdiction under 28 U.S.C. §§ 1331, 1346 and 2201. Defendants argue that this court lacks subject matter jurisdiction under §§ 1331 and 1346. This is because plaintiff's claims arise under the Medicare Act. This court has jurisdiction over a complaint arising under the Medicare Act only after the plaintiff has satisfied the requirements of § 405(g) which is incorporated into the Medicare Act by 42 U.S.C. §§ 1395cc(h)(1). Defendants contend that plaintiff has not satisfied the § 405(g) requirements.

Plaintiff contests this court has jurisdiction for four separate reasons. First, the claims do not arise under the Medicare Act. Second, an administrative appeals tribunal cannot hear constitutional and statutory challenges. Third, there is no other avenue of judicial

review for plaintiff's due process claims and thus the exception noted in *Michigan Academy v. Bowen*, 476 U.S. 667, 106 S. Ct. 2133, 90 L.Ed.2d 623 (1986), applies to them. Fourth, Counts I through III allege claims under the Medicaid Act which unlike the Medicare Act does not incorporate the 42 U.S.C. §§ 405(g) and 405(h) jurisdictional provisions of the Social Security Act. Plaintiff is incorrect and the complaint will be dismissed for lack of subject matter jurisdiction.

Plaintiff first argues that its claims do not arise under the Medicare Act and are thus not barred by the jurisdictional requirements of 42 U.S.C. §§ 405(g) and 405(h).

Under § 405(h)(which is incorporated into the Medicare Act by 42 U.S.C. § 1395ii), federal courts do not have subject matter jurisdiction under § 1346 and § 1331 over claims arising under the Medicare Act. *Michigan Association v. Donna Shalala*, 931 F.Supp. 1339, 1342 (E.D.Mich.1996) (quoting *Livingston Care Center, Inc. v. United States*, 934 F.2d 719, 721 (6th Cir.1991)). Section 405(h)'s "claims arising under" language has been defined to "include any claims in which both the standing and the substantive basis for the presentation of the claims is the Medicare Act." *Id.* (quoting *Heckler v. Ringer*, 466 U.S. 602, 615, 104 S. Ct. 2013, 80 L.Ed.2d 622 (1984)).

Count V of plaintiff's complaint alleges defendants did not satisfy their duties under a specific Medicare Act provision. 42 U.S.C. § 1395i-3(g)(2)(D). This count is barred by § 405(h) because it is directly based on a Medicare Act provision.

The resolution of the claims alleged in Counts IV, VI, and VII largely depends on an analysis of various Medicare Act provisions. Plus, any resolution will have a direct impact on the applicability and enforceability of the Medicare Act. Thus, Counts IV, VI, and VII are also barred by § 405(h) because they are substantively based on the Medicare Act. *Id.*

Plaintiff next contends that its constitutional and statutory challenges cannot be brought before an administrative appeals body. Under 42 C.F.R. § 488.408, the Secretary of HHS will not hear appeals concerning the manner and method of the surveys and the choice of remedy. However, § 405(h) allows for and requires that constitutional and statutory challenges satisfy the jurisdictional requirements of § 405(g) before a complaint can be brought to court. 42 U.S.C. § 405(h). This gives the Secretary an opportunity prior to constitutional litigation to determine whether plaintiff's claims are either invalid or resolvable under some other provision of the Medicare Act. *Weinberger v. Salfi*, 422 U.S. 749, 95 S. Ct. 2457, 45 L.Ed.2d 522 (1975). Therefore, it is not only constitutional, but reasonable to have constitutional and statutory challenges go through the jurisdictional requirements of the Medicare Act. *Id.*

Also, at the heart of plaintiff's case, is a claim for benefits. This is evidenced by the relief sought by plaintiff. Plaintiff seeks continuation of Medicare payments and reimbursement for past due payments incurred by the patients at the nursing homes. Thus, the issue here is whether or not the nursing homes are entitled to benefits. Plaintiff may not circumvent the Medicare Act by attempting to bring what is essentially

a claim for benefits as a facial constitutional challenge. *Id. Heckler*, 466 U.S. at 616.

Plaintiff next argues that even if the claims arise under the Medicare Act and the Secretary has jurisdiction over the constitutional and statutory challenges, §§ 405(g) and 405(h) do not apply because of the exception noted in *Michigan Academy*, 476 U.S. 667, 106 S. Ct. 2133, 90 L.Ed.2d 623 (1986).

In *Michigan Academy*, the Supreme Court was addressing Medicare Part B. Defendant contended that the Supreme Court's jurisdiction was barred by § 405(h). At the time, HHS did not offer an appeals process for its Part B participants. It was because the plaintiff had "no other avenue of judicial review" that the Court ruled §§ 1331 and 1346 gave federal courts jurisdiction over the Part B claims despite the jurisdictional bars of the Medicare Act.

The Medicare Act has now been amended to provide Part A and Part B participants the right to appeal within HHS. 42 U.S.C. § 405(h); 42 C.F.R. § 488.408(g). Section 405(h) allows plaintiff to appeal any dispute to the Secretary. Thus, the concern noted in *Michigan Academy* no longer exists because all participants now have an avenue of judicial review within HHS.

Having established that this case falls under the Medicare Act and that the *Michigan Academy* exception does not apply, it is now necessary to look at the jurisdictional requirements of the Act.

Under § 405(g), a Medicare participant must satisfy two requirements before bringing a case to court. The

first is a non-waivable requirement of presentment to the Secretary of HHS. The second is a waivable requirement of exhaustion of remedies. 42 U.S.C. § 405(g); *Martin v. Shalala*, 63 F.3d 497, 503 (7th Cir. 1995).

The first requirement has not been satisfied. Plaintiff has not alleged or shown any attempt at presentment of his claims to the Secretary. Therefore, it is unnecessary to even reach the second requirement.

As stated above, plaintiff's claims arise under the Medicare Act. Therefore, under § 405(h), HHS has jurisdiction over all of plaintiff's claims, including its constitutional and statutory challenges. The exception to § 405(h) noted in *Michigan Academy* does not apply since an avenue of judicial review exists for plaintiff. Therefore, failure by plaintiff to satisfy the presentment requirement of § 405(g) means this court lacks subject matter jurisdiction over the claims in plaintiff's complaint.

Plaintiff also represents nursing homes which only receive Medicaid benefits. The Medicaid Act does not contain any jurisdictional restrictions similar to those contained in §§ 405(g) and 405(h). Therefore, plaintiff argues, this Court has jurisdiction over the first three counts of their complaint which arise under the Medicaid Act.

This court does not agree. Counts I through III of the Complaint mirror Counts IV through VI. The issues are the same, the only difference being that the first three counts arise under the Medicaid Act whereas the latter three arise under the Medicare Act. By

reaching the merits on the Medicaid claims, this court would effectively resolve the Medicare issues as well. This attempt to back-door the jurisdictional bar of the Medicare Act is impermissible. *Rhode Island v. Califano*, 585 F.2d 1153, 1162-63 (1st Cir. 1978).

In *Rhode Island v. Califano*, the court held that federal courts lacked subject matter jurisdiction over Medicaid claims under circumstances similar to those at bar. In so ruling, the court reasoned that the Medicaid claims were not sufficiently separate and distinct from the Medicare claims. Any resolution of the Medicaid issues would unavoidably touch upon substantive Medicare issues. This, the court ruled, cannot be allowed under § 405(h).

Further, the Medicaid issues will be addressed when the Medicare claims are appealed to and heard by the Secretary. *Rhode Island*, 585 F.2d. at 1163. The result of such an appeal will have the same impact on both the Medicare and Medicaid claims because the Secretary's decision is based on regulations which provide a single set of requirements that both Medicare and Medicaid participants must satisfy. *Michigan Association*, 931 F.Supp. at 1345, 42 C.F.R. § 483. 1(b). Thus, the counts arising under the Medicaid Act have the same avenue of judicial review within HHS as the counts arising under the Medicare Act. As stated above, this appeals process must be completed before this court has jurisdiction over the claims plaintiff alleges in its complaint.

For the foregoing reasons, all claims against defendants will be dismissed for lack of subject matter jurisdiction.

ORDERED: The motion to dismiss of defendants, Donna E. Shalala, Anthony J. Tirone, and John R. Lumpkin [13-1] is granted. All counts of the complaint of plaintiff, Illinois Council for Long Term Care, are dismissed. Defendants' alternative motion for summary judgment [13-2] is denied as moot. Plaintiff's motion for a preliminary injunction [19-1] is denied as moot. The document being recorded in the docket as a motion for summary judgment by American Health Care Association [27-2] is a mislabeled memorandum and so is administratively terminated.

/s/ **GEORGE W. LINDBERG**
GEORGE W. LINDBERG
District Judge

APPENDIX C

UNITED STATES COURT OF APPEALS
FOR THE SEVENTH CIRCUIT
CHICAGO, ILLINOIS 60604

No. 97-2315
No. 96 C 2923

ILLINOIS COUNCIL ON LONG TERM CARE
INC., PLAINTIFF-APPELLANT

v.

DONNA E. SHALALA, SECRETARY OF HEALTH AND
HUMAN SERVICES, ET. AL., DEFENDANTS-APPELLEES

*APPEAL FROM THE UNITED STATES
DISTRICT COURT FOR THE NORTHERN DISTRICT
OF ILLINOIS, EASTERN DIVISION*

[August 13, 1998]

BEFORE: HON. FRANK H. EASTERBROOK,
Circuit Judge
HON. DIANE P. WOOD, Circuit Judge
HON. TERENCE T. EVANS, Circuit Judge

ORDER

Federal defendants-appellees filed a petition for rehearing and suggestion of rehearing en banc on June 22, 1998. All of the judges on the panel have voted to deny rehearing. A judge in active service called for a vote on suggestion of rehearing en banc,* but a majority** of the active judges voted to reject the suggestion. The petition for rehearing is therefore denied, and the suggestion for rehearing en banc is rejected.

* Judge Flaum did not participate in the consideration of the suggestion for rehearing en banc.

** Judges Ripple, Manion and Rovner voted to grant rehearing en banc.

APPENDIX D

1. Section 405(g) of Title 42, United States Code, provides:

Judicial review

Any individual, after any final decision of the Commissioner of Social Security made after a hearing to which he was a party, irrespective of the amount in controversy, may obtain a review of such decision by a civil action commenced within sixty days after the mailing to him of notice of such decision or within such further time as the Commissioner of Social Security may allow. Such action shall be brought in the district court of the United States for the judicial district in which the plaintiff resides, or has his principal place of business, or, if he does not reside or have his principal place of business within any such judicial district, in the United States District Court for the District of Columbia. As part of the Commissioner's answer the Commissioner of Social Security shall file a certified copy of the transcript of the record including the evidence upon which the findings and decision complained of are based. The court shall have power to enter, upon the pleadings and transcript of the record, a judgment affirming, modifying, or reversing the decision of the Commissioner of Social Security, with or without remanding the cause for a rehearing. The findings of the Commissioner of Social Security as to any fact, if supported by substantial evidence, shall be conclusive, and where a claim has been denied by the Commissioner of Social Security or a decision is rendered under subsection (b) of this section which is adverse to an individual who was a party to the hearing before the Commissioner of Social Security, because of failure of

the claimant or such individual to submit proof in conformity with any regulation prescribed under subsection (a) of this section, the court shall review only the question of conformity with such regulations and the validity of such regulations. The court may, on motion of the Commissioner of Social Security made for good cause shown before the Commissioner files the Commissioner's answer, remand the case to the Commissioner of Social Security for further action by the Commissioner of Social Security, and it may at any time order additional evidence to be taken before the Commissioner of Social Security, but only upon a showing that there is new evidence which is material and that there is good cause for the failure to incorporate such evidence into the record in a prior proceeding; and the Commissioner of Social Security shall, after the case is remanded, and after hearing such additional evidence if so ordered, modify or affirm the Commissioner's findings of fact or the Commissioner's decision, or both, and shall file with the court any such additional and modified findings of fact and decision, and a transcript of the additional record and testimony upon which the Commissioner's action in modifying or affirming was based. Such additional or modified findings of fact and decision shall be reviewable only to the extent provided for review of the original findings of fact and decision. The judgment of the court shall be final except that it shall be subject to review in the same manner as a judgment in other civil actions. Any action instituted in accordance with this subsection shall survive notwithstanding any change in the person occupying the office of Commissioner of Social Security or any vacancy in such office.

2. Section 405(h) of Title 42, United States Code, provides:

Finality of Commissioner's decision

The findings and decision of the Commissioner of Social Security after a hearing shall be binding upon all individuals who were parties to such hearing. No findings of fact or decision of the Commissioner of Social Security shall be reviewed by any person, tribunal, or governmental agency except as herein provided. No action against the United States, the Commissioner of Social Security, or any officer or employee thereof shall be brought under section 1331 or 1346 of title 28 to recover on any claim arising under this subchapter.

3. Section 1395cc of Title 42, United States Code, provides in relevant part:

(h) Dissatisfaction with determination of Secretary; appeal by institutions or agencies; single notice and hearing

(1) Except as provided in paragraph (2), an institution or agency dissatisfied with a determination by the Secretary that it is not a provider of services or with a determination described in subsection (b)(2) of this section shall be entitled to a hearing thereon by the Secretary (after reasonable notice) to the same extent as is provided in section 405(b) of this title, and to judicial review of the Secretary's final decision after such hearing as is provided in section 405(g) of this title, except that, in so applying such sections and in applying section 405(l) of this title thereto, any reference therein to the Commissioner of Social Security or the Social Security Administration shall be considered a reference to the Secretary or the Department of Health and Human Services, respectively.

(2) An institution or agency is not entitled to separate notice and opportunity for a hearing under both section 1320a-7 of this title and this section with respect to a determination or determinations based on the same underlying facts and issues.

4. Section 1395ii of Title 42, United States Code, provides:

Application of certain provisions of subchapter II

The provisions of sections 406 and 416(j) of this title, and of subsections (a), (d), (e), (h), (i), (j), (k), and (l) of section 405 of this title, shall also apply with respect to this subchapter to the same extent as they are applicable with respect to subchapter II of this chapter, except that, in applying such provisions with respect to this subchapter, any reference therein to the Commissioner of Social Security or the Social Security Administration shall be considered a reference to the Secretary or the Department of Health and Human Services, respectively.

In The 981307 FEB 11 '99

Supreme Court of the United States

October Term, 1998

DONNA E. SHALALA,
SECRETARY OF HEALTH AND HUMAN SERVICES, ET AL.,
PETITIONERS,

v.

ILLINOIS COUNCIL ON LONG TERM CARE, INC.

On Petition For A Writ of Certiorari
To The United States Court of Appeals
For the Seventh Circuit

CONDITIONAL CROSS-PETITION
FOR A WRIT OF CERTIORARI

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2098

QUESTION PRESENTED

Whether the court of appeals erred in dismissing cross-petitioner's challenge to the vagueness of the regulations at 42 C.F.R. § 488.300 *et seq.* as unripe, where the challenged regulations have been enforced for over three years and where exhaustion of administrative remedies would be futile?

PARTIES TO THE PROCEEDING

For Cross-Petitioner's statement of "Parties to the Proceeding", see Brief in Opposition at II. As stated therein and in accordance with Supreme Court Rule 29.1, the Illinois Council on Long Term Care, Inc., states that it has no affiliated corporations, either as parent, subsidiary or otherwise.

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No. 98-1109

In The
SUPREME COURT OF THE UNITED STATES
October Term, 1998

DONNA E. SHALALA,
SECRETARY OF HEATHL AND HUMAN SERVICES, ET AL.,
PETITIONERS,

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To The United States Court of Appeals
For the Seventh Circuit

**CONDITIONAL CROSS-PETITION
FOR A WRIT OF CERTIORARI**

**CONDITIONAL CROSS-PETITION FOR
A WRIT OF CERTIORARI**

The Illinois Council on Long Term Care, Inc. (the "Council"), respectfully submits this conditional cross-petition for a writ of certiorari to review the judgment of the United States Court of Appeals for the Seventh Circuit in this case.

OPINIONS BELOW

The opinions below are reproduced in the Petitioner Shalala's Appendix ("Pet. App."). The opinion of the court of appeals is reported at 143 F.3d 1072. Pet. App. 1a-12a. The opinion of the district court opinion is unreported. Pet. App. 13a-21a.

JURISDICTION

The judgment of the court of appeals was entered on May 8, 1998. Petitioner Shalala filed a timely petition for a writ of certiorari on January 12, 1999. The jurisdiction of this Court is invoked under 28 U.S.C. § 1254(1).

STATUTORY PROVISIONS INVOLVED

For relevant statutory provisions, *see* Petitioner Shalala's Petition For a Writ of Certiorari at 2 and Respondent Council's Brief in Opposition at 1 ("Opp. Br.").

STATEMENT OF THE CASE

Respondent and cross-petitioner Illinois Council on Long Term Care, Inc., relies upon and incorporates by reference the Statement of the Case in Respondent's Brief in Opposition. The following additional facts are relevant to the issue raised in this conditional cross-petition.

When the Council filed its complaint below, the Secretary filed a motion to dismiss, or in the alternative, for summary judgment, contending that the district court lacked subject matter jurisdiction and that the Council failed to state a claim for which relief can be granted. In response, the Council filed a cross-motion for preliminary injunction. At the hearing on the motions, the district court considered only the Secretary's motion to dismiss for lack of jurisdiction. The district court then granted the motion to dismiss, denied the Secretary's alternative motion for summary judgment as moot, and also denied the Council's motion for preliminary injunction as moot. Pet. App. at 21a. The Council appealed that order. Accordingly, the procedural posture of the case before the Seventh Circuit was an appeal of an order granting a motion to dismiss for lack of subject matter jurisdiction.

The Seventh Circuit reversed the district court's dismissal for lack of subject matter jurisdiction regarding all counts of the complaint, both those arising under Medicare (Pet. App. 3a-7a), and those arising under Medicaid (Pet. App. 7a-9a). Nevertheless, the Seventh Circuit affirmed the dismissal of the counts in the amended complaint¹ that allege that the new regulations are unconstitutionally vague on *ripeness* grounds. Pet. App. 10a-12a. The Council seeks review of the Seventh Circuit's conclusion that the vagueness challenge is unripe.

Because this appeal arises from an order granting a motion to dismiss, the allegations of the Council's complaint are taken as true. The Council alleges that the regulations are unconstitutionally vague because of the Secretary's failure to define certain "scope and severity factors" inspectors use to determine whether a facility is in substantial compliance with the regulations. Am. Compl. ¶ 86. Those factors are set forth at 42 C.F.R. § 488.404. The factors also appear on an enforcement "grid" that is used by inspectors and is included in the State Operations Manual. Am. Compl. Ex. A. The grid was published in 59 Fed. Reg. 56183 (November 10, 1994). *See Grid, Appendix hereto at A-1 ("App.")*.

To determine whether the Council's vagueness challenge is ripe, it is necessary for this Court to understand how inspectors use the grid and the scope and severity factors. The "severity" factors are listed vertically on the left side of the grid and range from "No Actual Harm with Potential for Minimal Harm" to "Immediate Jeopardy to Resident Health or Safety." The "scope" factors, listed horizontally across the bottom of the grid, are "Isolated," "Pattern" and "Widespread." When an inspector encoun-

¹ Amended Complaint, Counts I (Medicaid) and IV (Medicare).

ters a deficiency, he or she must determine which scope and severity factors to apply and then plot the deficiency in one of the boxes in the grid. "Substantial Compliance" exists only when the deficiency falls in boxes A, B, or C of the grid. On the other hand, "Substandard Quality of Care" may exist when a deficiency falls in boxes F, H, I, J, K, or L. Different remedies are imposed depending on the box wherein the deficiency is plotted. (See the Remedy Categories listed below the grid, and compare to actions that are "Required" and "Optional" within each box.) For example, if a deficiency is plotted in box F, denial of payment and/or civil money penalties of up to \$3,000 per day is required.

The only scope and severity factor that is defined in the regulations is "immediate jeopardy." 42 C.F.R. § 488.301. All the other factors are left undefined in the regulations. This lack of specificity has resulted in arbitrary and discriminatory enforcement of the regulations. Am. Compl. ¶ 87. Inspectors have complete discretion to determine the scope and severity factors for a deficiency. Inspectors can plot a deficiency in virtually any box in the grid and thereby instigate remedies on an *ad hoc*, subjective basis. Certain Illinois nursing facilities have been found out of compliance and providing "substandard quality of care," while others with the same types of deficiencies have been found in "substantial compliance." Am. Compl. ¶ 87. This lack of definition, and the unfettered discretion of inspectors, deprives the Council's members of both fair enforcement of the regulations and fair notice of the deficiencies for which they may be penalized, in violation of their rights to due process under the Fifth and Fourteenth Amendments. Am. Compl. ¶ 88.

Under the regulations, a facility wishing to appeal an enforcement remedy cannot challenge the choice of the

remedy or the scope and severity designations. 42 C.F.R. § 488.408(g)(2) ("A facility may not appeal the choice of remedy, including the factors considered by HCFA or the State in selecting the remedy, specified in § 488.404."). Because the scope and severity of a remedy cannot be challenged in an administrative hearing, published decisions of administrative law judges or administrative appeal boards do not discuss scope and severity factors or whether a particular remedy is appropriate. Thus, no body of administrative law is evolving that clarifies the meaning or application of the scope and severity factors.

**REASONS FOR GRANTING
CONDITIONAL CROSS-PETITION FOR
WRIT OF CERTIORARI**

I. The Conditional Cross-petition Should Be Granted To Review The Ripeness Of The Council's Vagueness Challenge Because It Is An Important Issue That Is Intertwined With The Jurisdictional Issue Raised By The Secretary.

A. The Council's Vagueness Challenge Raises Issues Of Far-reaching Importance.

If this Court grants the Secretary's petition for writ of certiorari on the jurisdictional issue, it should also consider the ripeness of the Council's vagueness challenge. Thousands of nursing homes nationwide that participate in Medicare and Medicaid are regularly surveyed based on the enforcement grid. App. at 1a. If, as the Council contends, the grid and corresponding regulations are unconstitutionally vague, an entire industry is being unjustly impacted. Nursing homes are being deprived of fair enforcement of the regulations and fair notice of the deficiencies for which they will be penalized, in violation of their due process rights under the Fifth and Fourteenth Amendments. Am.

Compl. ¶ 88. Moreover, both the Secretary and nursing home residents have a substantial interest in ensuring that good nursing homes participating in Medicare and Medicaid are not terminated arbitrarily. Yet because of the vagueness of the regulations and the broad discretion given to inspectors, the government could potentially terminate provider agreements for the majority of nursing facilities participating in Medicare and Medicaid nationwide.

Ripeness is an important issue in actions like this one seeking declaratory and injunctive relief, and the lower courts need this Court's guidance regarding its application. "The injunctive and declaratory judgment remedies are discretionary, and courts traditionally have been reluctant to apply them to administrative determinations unless these are in the context of a controversy 'ripe' for judicial resolution." *Abbott Laboratories v. Gardner*, 387 U.S. 136, 148 (1967). If federal question jurisdiction exists for constitutional and statutory challenges to regulations, lower courts should not too hastily dismiss such challenges on ripeness grounds. Substantial constitutional violations could go uncorrected. On the other hand, limited judicial resources demand that courts not entertain jurisdiction in cases that are truly unripe. If this Court entertains the jurisdictional issue the Secretary proposes, the lower courts also need this Court's analysis of the ripeness the Council's claims.

B. The Jurisdictional And Ripeness Issues In This Case Are Interrelated.

The major considerations for determining whether jurisdiction exists for the Council's constitutional and statutory claims also bear on whether the Council's vagueness claim is ripe. This Court has stated that the ripeness doctrine and the application of jurisdiction precluding statutes like § 405(h) "dovetail neatly." See *Reno v. Catholic*

Social Services, Inc., 509 U.S. 43, 60 (1993). The jurisdictional and ripeness issues also "dovetail" here.

As demonstrated in the Council's Brief in Opposition, the Council's statutory and constitutional claims cannot be considered in the administrative review process. Opp. Br. at 3. That is a major reason why § 1331 jurisdiction exists. As this Court reiterated in *Thunder Basin Coal Company v. Reich*, 510 U.S. 200, 207 (1994), whether "a statute is intended to preclude initial judicial review is determined from the statute's language, structure, and purpose, its legislative history, and whether the claims can be afforded meaningful review." (emphasis added) (citations omitted). See also *McNary v. Haitian Refugee Center*, 498 U.S. 479, 484, 496-97 (1991) (concluding that the limited post-exhaustion judicial review provided by the INA could not adequately address the statutory and constitutional claims at issue).

This same consideration weighs heavily in analyzing ripeness. This Court recognized in *Reno v. Catholic Social Services, Inc.*, 509 U.S. 43 (1993), the link between the adequacy of administrative review and ripeness. *Reno* considered whether federal question jurisdiction existed for two class actions challenging INS regulations. This Court concluded that jurisdiction existed and was not barred by § 1255a(f) of the Immigration Reform and Control Act. *Reno*, 509 U.S. 56-57. However, this Court also concluded that certain class members' claims were not ripe because an adequate administrative review mechanism existed. The *Reno* Court observed that "plaintiffs do not argue that this limited scheme would afford them inadequate review of a determination based on the regulations they challenge. . ." *Id.* at 60-61. This Court also stated that "plaintiffs' situation is thus different from that of the '17 unsuccessful individual SAW applicants' in *McNary* whose procedural objections, we

concluded, could receive no practical judicial review within the scheme established by 8 U.S.C. § 1160(e)." *Reno*, 509 U.S. at 61 (citation omitted).

By contrast, the *Reno* Court found that claims by any class member subjected to a "front-desking" procedure would be ripe because he "would have no formal denial to appeal to the Associate Commissioner for Examinations nor would he have an opportunity to build an administrative record on which judicial review might be based." *Id.* 509 U.S. at 63-64 (following *McNary*). Hence, this Court has recognized that both jurisdiction and ripeness are determined to some extent by the adequacy of the administrative review mechanism to adjudicate the claims at issue. That is the situation here. Because the Secretary's administrative review system is inadequate to deal with the statutory and constitutional claims at issue, federal question jurisdiction exists, and the Council's vagueness challenge is ripe. In this case, the issues of jurisdiction and ripeness are closely related, and just resolution of this case requires this Court to consider both issues, just as it did in *Abbott Laboratories v. Gardner*, 387 U.S. 136, 149 (1967); *Toilet Goods Assn., Inc. v. Gardner*, 387 U.S. 158, 164 (1967); and *Reno v. Catholic Social Services, Inc.*, 509 U.S. 43 (1993).

II. Under This Court's Controlling Precedent, The Council's Vagueness Challenge Is Ripe For Adjudication.

The Seventh Circuit erred in concluding that the vagueness challenge was unripe. The basic rationale of the ripeness doctrine "is to prevent the courts, through avoidance of premature adjudication, from entangling themselves in abstract disagreements over administrative policies, and also to protect the agencies from judicial interference until an administrative decision has been formalized and its effects felt in a concrete way by the

challenging parties." *Abbott Laboratories v. Gardner*, 387 U.S. 136 148-49 (1967). This Court's long-standing test for ripeness is two-fold, "requiring us to evaluate both the fitness of the issues for judicial decision and the hardship to the parties of withholding court consideration." *Id.* at 149. This Court has relied on the *Abbott Laboratories* test repeatedly.² Under both *Abbott Laboratories* factors, the Council's vagueness challenge is ripe.

The issues are fit for judicial resolution for several reasons. First, these regulations have been in force since 1995 and under them nursing homes have been, and continue to be, surveyed regularly. Approximately 70% have been found deficient. Pet. App. 2a. This is not like the situation in *Ohio Forestry Association, Inc. v. Sierra Club*, 523 U.S. 726 (1998), where logging under the challenged land use plan could not occur until numerous procedural requirements were fulfilled, and where this Court concluded that the challenger could wait until the threatened harm was more imminent.

Second, the courts will not benefit by further administrative review. A district court reviewing a final decision by the secretary is limited to the administrative record. 42 U.S.C. § 405(g) ("The Court shall have power to enter, upon the pleadings and transcript of the record, a judgment affirming, modifying, or reversing

² E.g., *Ohio Forestry Association, Inc. v. Sierra Club*, 523 U.S. 726, 118 S.Ct. 1665, 1670 (1998); *Reno v. Catholic Social Services, Inc.*, 509 U.S. 43, 71 (1993) (O'Connor concurring) (citing *Thomas v. Union Carbide Agricultural Products Co.*, 473 U.S. 568, 581-82 (1985); *Pacific Gas & Elec. Co. v. State Energy Resources Conservation and Development Comm'n*, 461 U.S. 109 (1983); *EPA v. National Crushed Stone Assn.*, 449 U.S. 64, 72-73 (1980)).

the decision" (emphasis added)). The vagueness of the regulations cannot be challenged in the administrative review process. Administrative law judges have no power to entertain such claims. Opp. Br. at 3. Accordingly, there would not be an adequate "administrative record" regarding the vagueness of the regulations for a federal court to review on appeal. Moreover, a district court exercising § 1331 jurisdiction that is considering the vagueness of the regulations would benefit from having evidence of how the regulations have been applied in multiple situations. A trade association like the Council can offer substantial evidence regarding how the regulations have been applied against its members in different situations to prove vagueness. This Court recognized in *McNary* that a federal district court sitting as a trial court would be in a superior position to entertain such a challenge compared to a court limited to an administrative record: "Not only would a court of appeals reviewing an individual SAW determination therefore most likely not have an adequate record as to the pattern of INS' allegedly unconstitutional practices, but it also would lack the fact finding and record-developing capabilities of a federal district court." *McNary*, 498 U.S. at 497. A federal district court exercising § 1331 jurisdiction, with its fact-finding and record-developing capabilities, is a better forum to consider a constitutional vagueness challenge than a federal court considering an individual administrative appeal under § 405(g).

Third, the Council's vagueness challenge attacks a widespread systemic problem — the Secretary's failure to adequately define the scope and severity factors. The vagueness of the regulations is readily apparent from the general failure to provide concrete definitions. The issue need not be distilled through some prolonged and futile administrative appeal. "[T]his is not a situation in which

consideration of the underlying legal issues would necessarily be facilitated if they were raised in the context of a specific attempt to enforce the regulations." *Gardner v. Toilet Goods Assn., Inc.*, 387 U.S. 167, 171 (1967). The issue is fit for judicial resolution.

Moreover, withholding court consideration would be burdensome to the Council's members, the second factor in the *Abbott Laboratories* analysis. Under the administrative review mechanism, the only way to preserve appeal rights is to refuse to correct an alleged deficiency and risk termination of one's provider agreement. Opp. Br. at 2. Even if a nursing home did refuse to correct a deficiency and appealed the matter through the administrative process, it would have virtually no opportunity to create an administrative record to support its vagueness challenge that a federal court could review on appeal thereafter.

For all these reasons the Council's vagueness challenge meets the *Abbott Laboratories* test for ripeness. The Seventh Circuit failed to apply the *Abbott Laboratories* test and its decision on ripeness should therefore be reversed.

III. The Seventh Circuit's Ripeness Analysis Is Flawed Because There Will Be No Administrative Law Decisions To Clarify The Regulations With The Passage Of Time.

Rather than applying the *Abbott Laboratories* factors to determine ripeness, the Seventh Circuit relied on the concept that "[a]gencies may use ambiguous standards that acquire meaning through the process of application, just as the common law does." Pet. App. 10a. (citing cases). The court also said that the Council "cannot ask for an all-at-once review but must wait until the agency has worked through the process of adding detail in administrative adjudication." Pet. App. 11a. Such reasoning *assumes* that

standards will get clearer over time through administrative decisions. That assumption does not apply here.

Under the regulations, a facility wishing to appeal an enforcement remedy cannot challenge the choice of the remedy or the scope and severity designations. 42 C.F.R. § 488.408(g)(2) ("A facility may not appeal the choice of remedy, including the factors considered by HCFA or the State in selecting the remedy, specified in § 488.404."). Because the scope and severity of a remedy cannot be challenged in an administrative hearing, published decisions of administrative law judges do not discuss scope and severity factors or the appropriateness of a particular remedy. Thus, no body of administrative law is evolving that clarifies the meaning or application of the scope and severity factors. By failing to define the scope and severity factors, and by giving inspectors *unreviewable* discretion to select remedies, the Secretary has ensured that the standards will remain subjective and unclear. In these circumstances, exhaustion of administrative remedies is futile, and therefore, the issue is ripe.

The Seventh Circuit also said the Council cannot mount a vagueness challenge without "facts of the case at hand." Pet. App. 10a (citing cases). The court seems to imply that the Council's complaint fails because it did not set forth specific fact scenarios wherein remedies were imposed. However, this confuses the "notice pleading" requirements with the burden of proof at trial. The Council's complaint satisfied the notice pleading standards of FRCP 8(a). The complaint need not have alleged individual fact patterns to state a claim that the regulations were vague. At trial, the Council can provide multiple examples of how the regulations have been randomly applied against its members. Federal courts are not to invent "heightened pleading standards" beyond the usual pleading requirements of FRCP

8(a). *Leatherman v. Tarrant County Narcotics Intelligence & Coordination Unit*, 507 U.S. 163 (1993) (courts may not apply a heightened pleading standard in civil rights cases alleging municipal liability under 42 U.S.C. § 1983). The Seventh Circuit should at least have remanded the vagueness counts for further factual development to determine ripeness, as it did with the due process claim. Pet. App. at 12a. Outright dismissal without giving leave to amend was clearly erroneous, especially after having concluded that jurisdiction existed for the claim. It was also contrary to this Court's approach in *Reno v. Catholic Social Services, Inc.*, 509 U.S. 43, 66-67 (1993) (remanding for district courts to determine which class members were front-desked for purposes of determining ripeness).

CONCLUSION

For the foregoing reasons, the conditional cross-petition should be granted and the dismissal of the Council's challenge to the vagueness of the regulations should be reversed.

Respectfully Submitted,

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 Illinois Council on Long Term
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February 1999

Immediate Jeopardy to
 Resident Health or
 Safety

Actual Harm that is
 not Immediate Jeopardy

No Actual Harm with
 Potential for More
 than Minimal Harm that is
 not Immediate Jeopardy

No Actual Harm with
 Potential for
 Minimal Harm

J PoC	K PoC	L PoC
Required: Cat. 3	Required: Cat. 3	Required: Cat. 3
Optional: Cat. 1	Optional: Cat. 1	Optional: Cat. 2
Optional: Cat. 2	Optional: Cat. 2	Optional: Cat. 1

G PoC	H PoC	I PoC
Required* Cat. 2	Required* Cat. 2	Required* Cat. 2
Optional: Cat. 1	Optional: Cat. 1	Optional:

D PoC	E PoC	F PoC
Required* Cat. 1	Required* Cat. 1	Required* Cat. 2
Optional: Cat. 2	Optional: Cat. 2	Optional: Cat. 1

No PoC	No Remedies	PoC
Commitment to Correct		
Not on HCFA-2567		PoC

Isolated Pattern Widespread

[REDACTED] Substandard quality of care: any deficiency in §483.13 Resident Behavior and Facility Practices, §483.15 Quality of Life, or in §483.25, Quality of Care that constitutes: immediate jeopardy to resident health or safety; or, a pattern of or widespread actual harm that is not immediate jeopardy; or, a widespread potential for more than minimal harm that is not immediate jeopardy, with no actual harm.

[REDACTED] Substantial compliance

REMEDIY CATEGORIES

Category 1 (Cat. 1)

Directed Plan of Correction
 State Monitor; and/or
 Directed In-Service Training

Category 2 (Cat. 2)

Denial of Payment for New
 Admissions;
 Denial of Payment for All Individuals
 Imposed by HCFA;
 and/or
 Civil Money Penalties:
 \$50 - \$3,000/day

Category 3 (Cat. 3)

Temporary Management
 Termination
 Optional:
 Civil Money Penalties
 \$3,000 - \$10,000/day

Denial of Payment for New Admissions must be imposed when a facility is not in substantial compliance within 3 months after being found out of compliance.

Denial of Payment and State Monitoring must be imposed when a facility has been found to have provided substandard quality of care on three consecutive standard surveys.

Note: Termination may be imposed by the State or HCFA at any time when appropriate.

* Required only when decision is made to impose alternative remedies instead of or in addition to termination.

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F I L E D

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In The

Supreme Court of the United States

October Term, 1998

DONNA E. SHALALA,
SECRETARY OF HEALTH AND HUMAN SERVICES, ET AL.,
PETITIONERS,

v.

ILLINOIS COUNCIL ON LONG TERM CARE, INC.

**On Petition For A Writ of Certiorari
To The United States Court of Appeals
For the Seventh Circuit**

RESPONDENT'S BRIEF IN OPPOSITION

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308P

QUESTION PRESENTED

Whether 42 U.S.C. § 405(h), incorporated into the Medicare Act by 42 U.S.C. § 1395ii, eliminates jurisdiction under 28 U.S.C. §§ 1331 and 1346 over an action asserting constitutional and statutory challenges to Medicare regulations where the contentions alleged cannot be considered in the administrative review process and are unrelated to an individual claim?

PARTIES TO THE PROCEEDINGS

The Secretary's statement of "Parties to the Proceeding" is accurate as to the Petitioners. Respondent is the Illinois Council on Long Term Care, Inc.

The Illinois Council on Long Term Care, Inc., an Illinois not-for-profit corporation, in compliance with Supreme Court Rule 29.1, states that it has no affiliated corporations, either as a parent, subsidiary or otherwise.

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No. 98-1109

In The
SUPREME COURT OF THE UNITED STATES
October Term, 1998

DONNA E. SHALALA,
SECRETARY OF HEATLH AND HUMAN SERVICES, ET AL.,
PETITIONERS,

v.
ILLINOIS COUNCIL ON LONG TERM CARE, INC.

On Petition For A Writ of Certiorari
To The United States Court of Appeals
For the Seventh Circuit

RESPONDENT'S BRIEF IN OPPOSITION

Respondent, the Illinois Council on Long Term Care, Inc., respectfully requests that this Court grant the petition for a writ of certiorari seeking review of the Seventh Circuits Opinion in this case. That opinion is reported at 143 F.3d 1072. However, the petition should be considered separately from *Your Home Nurse Services, Inc. v. Shalala*, No. 97-1489 (argued Dec. 2, 1998).

STATUTORY PROVISIONS INVOLVED

The provisions of 42 U.S.C. §§ 405(g), 405(h), 1395cc(h), and 1395ii are reproduced at Petitioner's Appendix to Petition at 24a-27a (hereinafter "Pet. App.").

The relevant provisions of 42 C.F.R. §§ 405.860, 488.408, and 498.3 are reproduced herein at Appendix, *infra*, A1-A8.

STATEMENT OF THE CASE

The Secretary's Statement of the Case omitted several important points. In 1987, Congress amended the Social Security Act with the Omnibus Budget Reconciliation Act, Pub. L. No. 100-203, 101 Stat. 1330 (1987). *See Pet. App.* at 14a. The amendments called for stricter guidelines and more severe penalties for providers not satisfying minimum health and safety standards. *Id.*; *See 42 U.S.C. § 1395i-3.* Implementing regulations for the 1987 amendments, however, did not take effect until July 1, 1995. *Pet. App.* at 1a. Before the new regulations went into effect, only 6% of nursing homes in Illinois were found to be out of compliance with the requirements to participate in Medicare and Medicaid. *Pet. App.* at 14a. After the new regulations went into effect in 1995, nearly 70% of nursing homes in Illinois were found deficient. *Pet. App.* at 2a, 14a. Respondent filed suit in district court asserting constitutional and statutory challenges to the new regulations.

Respondent contends that the drastic change in the rate of noncompliance is because the new regulations are vague and leave too much discretion to inspectors. *Pet. App.* at 2a. Respondent contends that the State Operations Manual used by inspectors has the effect of a regulation and therefore could be adopted only after notice-and-comment rulemaking under the Administrative Procedure Act, 5 U.S.C. § 553. *Pet. App.* at 2a. Respondent also contends that the administrative appeals process under the new regulations is so restrictive that it violates due process. *Pet. App.* at 2a. Administrative appeal rights are triggered only by imposition of a "remedy." *See 42 C.F.R. § 498.3(b)(12).* If a provider cures the alleged deficiency before a remedy is imposed, it loses those appeal rights. Thus, when an inspection results in deficiencies, a provider must choose between (a) refusing to correct the alleged deficiency and

risking termination of its provider agreement in order to appeal the deficiency; or (b) remedying the alleged deficiency and thereby forfeiting appeal rights. In addition, providers have no right to appeal the imposition of State monitoring or the loss of approval for a nurse's-aid training program. 42 C.F.R. § 498.3(b)(12) and (d)(10)(iii). Providers also have virtually no right to challenge the scope and severity of alleged deficiencies. 42 C.F.R. § 498.3(d)(10)-(11). Providers may not appeal the choice of the remedy, including the factors considered in selecting the remedy. 42 C.F.R. § 488.408.

Significantly, providers also cannot assert the above mentioned claims nor challenge the new regulations themselves in the administrative review process. Administrative law judges are not empowered to hear such claims. *See 42 C.F.R. § 405.860.*¹⁴ Because administrative law judges cannot hear statutory or constitutional challenges, no "administrative record" is created regarding such claims for a federal court to review on appeal pursuant to 42 U.S.C. § 405(g). *Pet. App.* at 24a-25a. Furthermore, respondent, a trade association, is not entitled to any kind of administrative hearing on the constitutional and statutory claims asserted here.

Respondent's complaint asserted separate counts on behalf of its 75 members who participate solely in Medicaid,

¹⁴ *E.g., Bowen v. Michigan Academy of Family Physicians*, 476 U.S. 667, 676, n. 6 (1986). (Medicare manual specifically prohibits administrative law judge from commenting on constitutionality of Medicare Act or regulations); *American Ambulance Serv. v. Sullivan*, 911 F.2d 901, 905 (CA3 1990) (it is not within the authority of the hearing officers to pass on the legality of the policies established by agency), *aff'd. without opinion*, 947 F.2d 934 (CA3 1991).

and separate counts for the remainder who participate in both Medicare and Medicaid. Pet. at 7, n. 5. The district court dismissed all counts of the complaint for lack of subject matter jurisdiction. Pet. App. at 3a. The Seventh Circuit reversed the district court's conclusion that the Medicaid counts should be dismissed for lack of jurisdiction. Pet. App. at 7a-9a. The Secretary does not challenge that part of the Seventh Circuit's decision. See Pet. at 7, n. 5. Accordingly, the Seventh Circuit's conclusion (Pet. App. at 9a) that a Medicaid provider is not forbidden from bringing a pre-enforcement challenge under § 1331 to a Medicaid regulation is not before the Court and, therefore, will not be addressed below.

REASONS FOR GRANTING WRIT

I. The Certiorari Petition Should be Granted but Should not be “Held Pending” Disposition of *Your Home* Because *Your Home* Is Distinguishable and its Disposition Will not Govern this Case.

We agree that the Court should grant the Secretary's certiorari petition to resolve a genuine split in the circuits. The Court should also grant the petition because respondent has filed a conditional cross-petition to review the Seventh Circuit's dismissal of respondent's challenge to the vagueness of the regulations. As explained in the cross-petition, thousands of nursing homes nationwide are being subjected to an unconstitutionally vague enforcement system, and the Seventh Circuit should not have dismissed the vagueness claim. The Court also should reject the Secretary's invitation to “hold” the petition pending disposition of *Your Home Visiting Nurse Services, Inc. v. Shalala*, No. 97-1489 (argued Dec. 2, 1998) (hereinafter “*Your Home*”). *Your*

Home is highly distinguishable and its resolution will provide no guidance here. It would be inappropriate to attempt to resolve summarily the circuit split in this case by relying on *Your Home*.

A. The Seventh Circuit's Decision Conflicts With a Sixth Circuit Decision in an Essentially Identical Case.

We agree with the Secretary's contention (Pet. at 14-15) that the Seventh Circuit's decision squarely conflicts with *Michigan Assn. of Homes & Services for the Aging, Inc. v. Shalala*, 127 F.3d 496 (CA6 1997), *reh'g, en banc, denied*, 1997 U.S. App. LEXIS 37154 (CA6 Dec. 17, 1997) (“*Michigan Association*”). The Seventh Circuit declared “we disapprove the sixth circuit's decision in *Michigan Association* across the board . . .” Pet. App. at 8a. *Michigan Association* largely is indistinguishable from the Medicare members' claims in this case. The plaintiff in *Michigan Association* raised many of the same challenges as respondent's Medicare members regarding the same statutes and regulations. This case thus presents a clear circuit conflict on a significant jurisdictional issue.

We also agree with the Secretary's contention that the Seventh Circuit's decision conflicts with other court of appeals decisions that have limited the holding in *Bowen v. Michigan Academy of Physicians*, 476 U.S. 667 (1986) (“*Michigan Academy*”) in light of subsequent amendments to Part B of the Medicare program. Pet. at 15. There is disagreement among the lower courts regarding the effect of subsequent amendments on the holding in *Michigan Academy*. The district court below and the Sixth Circuit in *Michigan Association* concluded that the 1986 amendments eliminated the precedential value of *Michigan Academy*. Pet. App. at 5a, 18a; see also Pet. at 15 (citing cases).

But as the Seventh Circuit recognized, the 1986 amendments did not change the language of § 405(h) or § 1395ii. The operative language is the same as when *Michigan Academy* was decided. Pet. App. at 6a-7a. Other federal courts have reached the same conclusion: *Vermont Assembly of Home Health Agencies, Inc. v. Shalala*, 18 F. Supp. 2d 355, 362 (D. Vermont 1998) (even though the statutory scheme has been altered, this Circuit still recognizes that courts have subject matter jurisdiction over a challenge to a rule of general applicability); *Abbott Radiology Associates v. Sullivan*, 801 F. Supp. 1012, 1017-1018 (W.D.N.Y. 1992) ("the 1986 amendments did not displace the reasoning in *Michigan Academy* and courts have explicitly acknowledged *Michigan Academy's* continuing vitality"); *Abbey v. Sullivan*, 788 F. Supp. 165, 167 n.2 (S.D.N.Y. 1992), aff'd, 978 F.2d 37 (CA2 1992) ("contrary to defendant's assertions, the 1986 amendments to Medicare Part B do not render *Michigan Academy* a 'dead letter'"); *Griffeth v. Bowen*, 678 F. Supp. 942, 945 (D. Mass 1988) (there is no tension between *Michigan Academy* and the 1986 amendments). See also *United States, Qui Tam Body v. Blue Cross and Blue Shield of Alabama*, 156 F.3d 1098 (CA11 1998) (following *Michigan Academy* without suggesting that the 1986 amendments affected its holding). This case would be a good vehicle to resolve the confusion in the lower courts on this issue.

The issues raised here deserve careful consideration. Questions arise frequently regarding the scope of § 405(h)'s jurisdictional bar for statutory and constitutional challenges. Without clarification, the circuit split will spawn confusion in the lower courts and consume an increasing amount of judicial resources. Through this case the Court can shed light on a jurisdictional issue of widespread importance for both a federal agency and for providers nationwide that participate in Medicare. Moreover, the cir-

cuit split should be resolved promptly, because it encourages government officials to administer the same federal program in a nonuniform manner. Officials could apply excessively rigorous enforcement techniques within circuits that do not recognize federal question jurisdiction for constitutional and statutory claims. The circuit split also will encourage forum shopping by plaintiffs seeking to challenge Medicare regulations. Resolving this circuit split based on the outcome in a *distinguishable* case like *Your Home* would be inappropriate.

B. Your Home Is Highly Distinguishable.

The main issue in *Your Home* is whether a nursing facility was entitled to *more administrative review* than the Medicare statute actually requires. It dealt only peripherally with federal question jurisdiction under § 1331. In *Your Home*, the facility challenged a fiscal intermediary's discretionary decision not to reopen a "cost report" used to determine Medicare reimbursement. *Your Home Visiting Nurses Services v. Shalala*, 132 F.3d 1135, 1137 (CA6 1997), cert. granted in part, 118 S. Ct. 2318 (U.S. 1998). The facility appealed to a Provider Reimbursement Review Board, but the Board said it lacked jurisdiction. The Board said a fiscal intermediary's decision not to reopen a cost report was unreviewable pursuant to a regulation. The facility appealed to district court alleging jurisdiction under § 405(g), and also under § 1331, citing to *Bowen v. Michigan Academy of Family Physicians*, 476 U.S. 667 (1986). The facility argued that the Board and/or the district court should have jurisdiction to review the intermediary's refusal to reopen the cost report. *Your Home*, 132 F.3d at 1140.

Your Home is distinguishable both from this case and from *Michigan Academy* because, among other reasons, the facility in *Your Home* was not asserting facial statutory and

constitutional challenges to any regulations. The Secretary so argued in her merits brief in *Your Home*:

[Petitioner's claim] does not attack the underlying validity of a regulation; it simply avers that the intermediary misapplied a regulation when determining the amount of reimbursable owners' compensation costs owed to petition. Thus, petitioner's contentions do not resemble the sort of facial challenge that the Court in *Michigan Academy* found to be beyond the scope of Section 405(h)'s preclusive effect.

Your Home, Respondent's Br. at 31, 1998 WL 644663. *Your Home* arguably involves the sort of "amount determinations" and "quite minor matters" that *Michigan Academy* said Congress meant to foreclose by section 405(h). See *Michigan Academy*, 476 U.S. 667, 680. By contrast, respondent's claims in this case are facial challenges to the underlying validity of the regulations and are "beyond the scope of Section 405(h)'s preclusive effect."

Your Home also is distinguishable because the facility had the right to appeal the amount of reimbursement within the administrative process, but failed to do so. See *Your Home*, Respondent's Br. at 12. The facility in *Your Home* also had access to 42 U.S.C. § 1395w(f)(1), a review mechanism that would allow it to challenge questions of law or regulations in federal court after a review board certified that it lacked authority to decide the question. See *Your Home*, Respondent's Br. at 11, n. 3 and 31. ("Section 1395oo explicitly affords Part A providers, such as petitioner, an avenue to challenge both the amount of Medicare payments and the methods by which those payments are calculated."). Here, neither respondent nor any of its members could raise their constitutional and statutory challenges in any administrative setting. Section 405(h) may well pre-

clude federal question jurisdiction over the fiscal intermediary's refusal to reopen a cost report in *Your Home*. But § 405(h) does *not* preclude jurisdiction over the constitutional and statutory claims alleged here. The disposition of *Your Home* will not govern this case. The certiorari petition should be granted, but this case should be considered separately from *Your Home*.

II. The Seventh Circuit's Jurisdictional Ruling Should Be Affirmed. The Court Followed Controlling Precedent In Concluding That Jurisdiction Exists Under Section 1331.

The Secretary argues the Seventh Circuit's decision conflicts with *Heckler v. Ringer*, 466 U.S. 602 (1984) ("Ringer") and that the court misconstrued *Michigan Academy* Pet. at 12-13. In fact, the court correctly followed this Court's more recent decisions in *Michigan Academy* and *McNary v. Haitian Refugee Center*, 498 U.S. 479 (1991), instead of *Ringer*, for several reasons.

First, *Ringer* is distinguishable from this case for the same reasons this Court cited when it distinguished *Ringer* in *McNary*, 498 U.S. at 494-496. *Ringer* involved claims for reimbursement for a surgical procedure that the Court concluded were not "collateral" to claims for benefits. Similar to the claimants in *Your Home*, the claimants in *Ringer* could have pursued administrative remedies for processing reimbursement claims, *id.* at 494, and had an adequate remedy in § 405(g) for challenging in court all aspects of the Secretary's denial of their claims for payment. *Id.* at 495. By contrast, the claims here *are* collateral to individualized or substantive claims for benefits and "respondents would not as a practical matter be able to obtain meaningful judicial review" of their claims after exhausting

administrative remedies. *McNary* 498 U.S. at 495-496.

Second, the court of appeals was right in following *Michigan Academy* and *McNary* instead of *Ringer*, because they are more recent and set forth an analysis that is more precise and truer to congressional intent than the analysis in *Ringer*. In *Michigan Academy*, this Court set forth an analysis for jurisdictional issues like those at issue here. “We begin with the strong presumption that Congress intends judicial review of administrative action.” 476 U.S. at 670-71. “[O]nly upon a showing of ‘clear and convincing evidence’ of a contrary legislative intent should the courts restrict access to judicial review.” *Id.* at 671. With those principles in mind, this Court analyzed the statutory provisions the Secretary claimed eliminated federal question jurisdiction. *Id.* at 673. Those same provisions are at issue here. The Court also considered the legislative history and concluded that federal question jurisdiction exists for matters that are not determined in an administrative hearing:

[c]areful analysis of the governing statutory provisions and their legislative history thus reveals that Congress intended to bar judicial review only of determinations of the amount of benefits to be awarded under Part B. Congress delegated this task to carriers who would finally determine such matters in conformity with the regulations and instructions of the Secretary. We conclude, therefore, that those matters which Congress did not leave to be determined in a “fair hearing” conducted by the carrier—including challenges to the validity of the Secretary’s instructions and regulations—are not impliedly insulated from judicial review....

Michigan Academy, 476 U.S. at 678. The foregoing language and similar statements in *Michigan Academy* constitute the critical holding the Seventh Circuit followed

here. See Pet. App. at 4a. The Seventh Circuit simply followed, in straightforward fashion, this Court’s interpretation of particular statutes and their legislative history.

This Court employed the same analysis and followed *Michigan Academy* five years later in *McNary v. Haitian Refugee Center*, 498 U.S. 479 (1991). In *McNary*, this Court upheld federal question jurisdiction over systemic and constitutional challenges to regulatory procedures adopted under the Immigration Reform Act (“IRA”). As in *Michigan Academy*, this Court analyzed the language of the statute and the administrative review scheme. This Court recognized that the administrative review provisions of the IRA were tailored to individual determinations of “an application” and a denial thereof. *McNary* at 492. The review provisions did not refer “to general collateral challenges to unconstitutional practices and policies used by the agency in processing applications.” *Id.*

McNary further discussed and followed *Michigan Academy*: “[In *Michigan Academy*] [w]e recognized that review of individual determinations of the amount due on particular claims was foreclosed, but upheld the collateral attack on the regulation itself, emphasizing the critical difference between an individual ‘amount determination’ and a challenge to the procedures for making such determinations.” *McNary*, 498 U.S. at 498. “Decision in this case is therefore supported by our unanimous holding^{2/} in *Bowen* [v. *Michigan Academy*].” *Id.* at 497.

This Court’s more recent decisions continue to follow or cite to *Michigan Academy* and *McNary*, confirming their analytical approach. *Reno v. Catholic Soc. Servs.*, 509 U.S. 43, 63-64 (1993) (“As we stated recently in *McNary*, there

^{2/} Chief Justice Rehnquist did not participate in the case.

is a ‘well-settled presumption favoring interpretations of statutes that allow judicial review of administrative action’” also citing *Michigan Academy*); *Thunder Basin Coal Company v. Reich*, 510 U.S. 200, 213 (1994) (citing *Michigan Academy* and discussing but distinguishing *McNary*); *Gutierrez De Martinez v. Lamagno*, 515 U.S. 417, 424 (1995) (“federal judges traditionally proceed from the ‘strong presumption that Congress intends judicial review.’”, citing *Michigan Academy*). The Seventh Circuit correctly applied the analysis from this Court’s more recent cases, and concluded that jurisdiction exists for respondent’s claims.

The Secretary says *Michigan Academy* does not support jurisdiction here because § 405(g) expressly confirms the district court’s power to “review . . . the validity of [the Secretary’s] regulations” when it reviews the Secretary’s final decision. Pet. at 13-14. This Court rejected the same argument in *McNary*. In *McNary*, the Immigration and Naturalization Act provided for administrative review and thereafter judicial review by the court of appeals regarding decisions on amnesty applications. This Court concluded that the limited post-exhaustion judicial review provided by the INA could not adequately address the statutory and constitutional claims at issue. *McNary*, 498 U.S. at 484, 496-97. This Court recognized that administrative and judicial review of an agency decision “is almost always confined to the record made in the proceeding at the initial decision making level.” *Id.* at 496. This Court noted that the lack of an adequate administrative record at the initial decision-making level meant that the court of appeals would have no “meaningful basis upon which to review application determinations.” *Id.* at 497.

The same analysis applies here. Respondent’s statutory and constitutional claims cannot be considered in the administrative review process. Administrative law judges

have no authority to hear statutory or constitutional challenges to regulations.^{3/} Accordingly, there would be no evidence taken and no administrative record compiled regarding respondent’s statutory and constitutional claims for a federal court to review in an appeal pursuant to § 405(g). As in *McNary*, restricting judicial review to the limited scope of § 405(g) “is the practical equivalent of total denial of judicial review of generic constitutional and statutory claims.” *McNary* at 497. As the Court reiterated in *Thunder Basin Coal Company v. Reich*, 510 U.S. 200, 207 (1994), whether “a statute is intended to preclude initial judicial review is determined from the statute’s language, structure, and purpose, its legislative history, and whether the claims can be afforded meaningful review.” (emphasis added) (citations omitted). Respondent’s claims here cannot be meaningfully addressed or reviewed in the administrative process. Under *McNary* and *Michigan Academy*, jurisdiction exists under § 1331.

B. The Sixth Circuit’s Conflicting Decision Failed to Follow Controlling Precedent and Should be Overruled.

The Sixth Circuit’s decision in *Michigan Association*, 127 F.3d 496 (CA6 1997), failed to follow the analysis set forth in *McNary* and other recent Supreme Court cases. The Sixth Circuit tried to distinguish *McNary*, stating that the *McNary* claimants had no meaningful judicial review, but that the claimant in *Michigan Association* did have

^{3/} E.g., *Bowen v. Michigan Academy of Family Physicians*, 476 U.S. 667, 676, n. 6 (1986); *American Ambulance Serv. v. Sullivan*, 911 F.2d 901, 905 (CA3 1990), aff’d without opinion, 947 F.2d 934 (CA3 1991).

meaningful judicial review. 127 F.3d at 501. The Sixth Circuit failed to recognize, however, that statutory and constitutional challenges *cannot* be raised in administrative proceedings, and therefore, an adequate administrative record for a federal court to review on appeal will never be created.

The Sixth Circuit also tried to distinguish *McNary*, stating that the statutory language at issue in *McNary* regarding "a determination respecting an application for adjustment of status" is much more restrictive than the language of § 405(h). 127 F.3d at 501. However, the provision at issue in *McNary* is very similar to 42 U.S.C. § 1395cc(h)(1), which incorporates § 405(g) into the Medicare Act, regarding "a determination of the Secretary that it is not a provider of services." That language is just as indicative of individualized determinations as the language in *McNary*. The Sixth Circuit's attempt to distinguish *McNary* is therefore meritless.

C. The Seventh Circuit's Decision Is Consistent with Recent Supreme Court and Circuit Court Cases.

The Secretary contends that the Seventh Circuit's decision conflicts with the great weight appellate authority. Pet. at 14. As demonstrated above, the court's decision is consistent with the great weight of recent Supreme Court authority, particularly *Michigan Academy*, *McNary*, and *Reno v. Catholic Social Services, Inc.*, 509 U.S. 43 (1993). Compare *Thunder Basin Coal Company v. Reich*, 510 U.S. 200 (1994) (distinguishing *McNary*).

The Seventh Circuit's decision also is consistent with a recent well reasoned decision from the Eleventh Circuit, *United States, Qui Tam Body v. Blue Cross and Blue Shield*

of Alabama, Inc., 156 F.3d 1098 (CA11 1998). There, the Eleventh Circuit analyzed *Weinberger v. Salfi*, 422 U.S. 749 (1975); *United States v. Erika, Inc.*, 456 U.S. 201 (1982); *Heckler v. Ringer*; and *Bowen v. Michigan Academy*, declaring:

Perhaps most clearly of the four Supreme Court cases analyzing the jurisdictional limitations contained in the Medicare Act, *Bowen* demonstrates that subsection 405(h), viewed within the context in which it was drafted and made applicable to Medicare, simply seeks to preserve the integrity of the administrative process Congress designed to deal with challenges to amounts determinations by dissatisfied beneficiaries, not to serve as a complete preclusion of all claims related to benefits determinations in general.

Body, 156 F.3d at 1109. The Eleventh Circuit concluded that actions "which do not seek payment from the government and could not be brought under Section 405, are therefore, not barred by subsection 405(h)." *Id.* at 1104. The Eleventh Circuit's decision is consistent with the Seventh Circuit's decision here, and accordingly, also conflicts with the Sixth Circuit's decision in *Michigan Association*.

The Secretary contends (Pet. at 15) that the court of appeals' decision is inconsistent with *St. Francis Medical Center v. Shalala*, 32 F.3d 805, 812-813 (CA3 1994), cert. denied, 514 U.S. 1016 (1995). *St. Francis* is distinguishable for the same reasons *Your Home* is distinguishable. In *St. Francis*, the court held that avenues of administrative review were available for claims regarding annual cost reports. 32 F.3d at 812 (discussing 42 U.S.C. § 1395oo(f)(1)). No such administrative review is available for the statutory and constitutional claims here.

CONCLUSION

For the foregoing reasons, the certiorari petition should be granted, but this case should be considered separately from *Your Home Visiting Nurse Services, Inc. v. Shalala*, No. 97-1489.

Respectfully submitted,

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February 1999

APPENDIX A

(1) Section 405.860 of Title 42, Code of Federal Regulations, provides:

Review of national coverage decisions (NCDs).

(a) General.

(1) HCFA makes NCDs either granting, limiting, or excluding Medicare coverage for a specific medical service, procedure or device. NCDs are made under section 1862(a)(1) of the Act or other applicable provisions of the Act. An NCD is binding on all Medicare carriers, fiscal intermediaries, PROs, HMOs, CMPs, and HCPPs when published in HCFA program manuals or the Federal Register.

(2) Under section 1869(b)(3) of the Act, only NCDs made under section 1862(a)(1) of the Act are subject to the conditions of paragraphs (b) through (d) of this section.

(b) Review by ALJ.

(1) An ALJ may not disregard, set aside, or otherwise review an NCD.

(2) An ALJ may review the facts of a particular case to determine whether an NCD applies to a specific claim for benefits and, if so, whether the NCD has been applied correctly to the claim.

(c) Review by Court.

(1) A court's review of an NCD is limited to whether the record is incomplete or otherwise lacks adequate information to support the validity of the decision, unless the case has been remanded to the Secretary to supplement the record regarding the NCD. The court may not invalidate an

NCD except upon review of the supplemented record.

(2) A Federal court may not hold unlawful or set aside an NCD because it was not issued in accordance with the notice and comment procedures of the Administrative Procedure Act (5 U.S.C. 553) or section 1871(b) of the Act.

(d) Remands--

(1) Secretary's action. When a court remands an NCD matter to the Secretary because the record in support of the NCD is incomplete or otherwise lacks adequate information, the Secretary remands the case to HCFA in order to supplement the record.

(2) Remand to HCFA. HCFA supplements the record with new or updated evidence, including additional information from other sources, and may issue a revised NCD.

(3) Final Actions.

(i) The proceedings to supplement the record, are expedited.

2. Section 488.408 of Title 42, Code of Federal Regulations, provides:

Selection of remedies.

(a) **Categories of remedies.** In this section, the remedies specified in Sec. 488.406(a) are grouped into categories and applied to deficiencies according to how serious the noncompliance is.

(b) **Application of remedies.** After considering the factors specified in Sec. 488.404, as applicable, if HCFA and the State choose to impose remedies, as provided in paragraphs (c)(1), (d)(1) and (e)(1) of this section, for facil-

ity noncompliance, instead of, or in addition to, termination of the provider agreement, HCFA does and the State must follow the criteria set forth in paragraphs (c)(2), (d)(2), and (e)(2) of this section, as applicable.

(c) Category 1.

(1) Category 1 remedies include the following:

- (i) Directed plan of correction.
- (ii) State monitoring.
- (iii) Directed in-service training.

(2) HCFA does or the State must apply one or more of the remedies in Category 1 when there--

(i) Are isolated deficiencies that constitute no actual harm with a potential for more than minimal harm but not immediate jeopardy; or

(ii) Is a pattern of deficiencies that constitutes no actual harm with a potential for more than minimal harm but not immediate jeopardy.

(3) Except when the facility is in substantial compliance, HCFA or the State may apply one or more of the remedies in Category 1 to any deficiency.

(d) Category 2.

(1) Category 2 remedies include the following:

- (i) Denial of payment for new admissions.
- (ii) Denial of payment for all individuals imposed only by HCFA.
- (iii) Civil money penalties of \$50-3,000 per day.

(2) HCFA applies one or more of the remedies in Category 2, or, except for denial of payment for all individuals, the State must apply one or more of the remedies in Category 2 when there are--

(i) Widespread deficiencies that constitute no actual harm with a potential for more than minimal harm but not immediate jeopardy; or

(ii) One or more deficiencies that constitute actual harm that is not immediate jeopardy.

(3) HCFA or the State may apply one or more of the remedies in Category 2 to any deficiency except when--

(i) The facility is in substantial compliance; or

(ii) HCFA or the State imposes a civil money penalty for a deficiency that constitutes immediate jeopardy, the penalty must be in the upper range of penalty amounts, as specified in Sec. 488.438(a).

(e) Category 3.

(1) Category 3 remedies include the following:

(i) Temporary management.

(ii) Immediate termination.

(iii) Civil money penalties of \$3,050-\$10,000 per day.

(2) When there are one or more deficiencies that constitute immediate jeopardy to resident health or safety--

(i) HCFA does and the State must do one or both of the following:

(A) Impose temporary management; or

(B) Terminate the provider agreement;

(ii) HCFA and the State may impose a civil money penalty of \$3,050-\$10,000 per day, in addition to imposing the remedies specified in paragraph (e)(2)(i) of this section.

(3) When there are widespread deficiencies that constitute actual harm that is not immediate jeopardy, HCFA and the State may impose temporary management, in addition to Category 2 remedies.

(f) Plan of correction.

(1) Except as specified in paragraph (f)(2) of this section, each facility that has a deficiency with regard to a requirement for long term care facilities must submit a plan of correction for approval by HCFA or the State, regardless of—

(i) Which remedies are imposed; or

(ii) The seriousness of the deficiencies.

(2) When there are only isolated deficiencies that HCFA or the State determines constitute no actual harm with a potential for minimal harm, the facility need not submit a plan of correction.

(g) Appeal of a certification of noncompliance.

(1) A facility may appeal a certification of noncompliance leading to an enforcement remedy.

(2) A facility may not appeal the choice of remedy, including the factors considered by HCFA or the State in selecting the remedy, specified in Sec. 488.404.

3. Section 498.3 of Title 42, Code of Federal Regulations, provides in pertinent part:

Scope and applicability.

(b) **Initial determinations by HCFA.** HCFA makes initial determinations with respect to the following matters:

(12) With respect to an SNF or NF, a finding of noncompliance that results in the imposition of a remedy specified in Sec. 488.406 of this chapter, except the State monitoring remedy, and the loss of the approval for a nurse-aide training program.

(d) **Administrative actions that are not initial determinations.** Administrative actions that are not initial determination (and therefore not subject to appeal under this part) include but are not limited to the following:

(1) The finding that a provider or supplier determined to be in compliance with the conditions or requirements for participation or for coverage has deficiencies.

(2) The finding that a prospective provider does not meet the conditions of participation set forth elsewhere in this chapter, if the prospective provider is, nevertheless, approved for participation in Medicare on the basis of special access certification, as provided in subpart B of part 488 of this chapter.

(3) The refusal to enter into a provider agreement because the prospective provider is unable to give satisfactory assurance of compliance with the requirements of title XVIII of the Act.

(4) The finding that an entity that had its provider agreement terminated may not file another agreement because the reasons for terminating the previous agreement

have not been removed or there is insufficient assurance that the reasons for the exclusion will not recur.

(5) The determination not to reinstate a suspended or excluded practitioner, provider, or supplier because the reason for the suspension or exclusion has not been removed, or there is insufficient assurance that the reason will not recur.

(6) The finding that the services of a laboratory are covered as hospital services or as physician's services, rather than as services of an independent laboratory, because the laboratory is not independent of the hospital or of the physician's office.

(7) The refusal to accept for filing an election to claim payment for all emergency hospital services furnished in a calendar year because the institution--

(i) Had previously charged an individual or other person for services furnished during that calendar year;

(ii) Submitted the election after the close of that calendar year; or

(iii) Had previously been notified of its failure to continue to comply.

(8) The finding that the reason for the revocation of a supplier's right to accept assignment has not been removed or there is insufficient assurance that the reason will not recur.

(9) The finding that a hospital accredited by the Joint Commission on Accreditation of Hospitals or the American Osteopathic Association is not in compliance with a condition of participation, and a finding that that hospital is no longer deemed to meet the conditions of participation.

(10) With respect to an SNF or NF-

(i) The finding that the SNFs or NFs deficiencies pose immediate jeopardy to the health or safety of its residents;

(ii) Except as provided in paragraph (b)(13) of this section, a determination by HCFA as to the facility's level of noncompliance; and

(iii) The imposition of State monitoring or the loss of the approval for a nurse-aide training program.

(11) The choice of alternative sanction or remedy to be imposed on a provider or supplier.

(12) The determination that the accreditation requirements of a national accreditation organization do not provide (or do not continue to provide) reasonable assurance that the entities accredited by the accreditation organization meet the applicable long-term care requirements, conditions for coverage, conditions of certification, conditions of participation, or CLIA condition level requirements.

(13) The determination that requirements imposed on a State's laboratories under the laws of that State do not provide (or do not continue to provide) reasonable assurance that laboratories licensed or approved by the State meet applicable CLIA requirements.

(14) The choice of alternative sanction or remedy to be imposed on a provider or supplier.

(15) A decision by the State survey agency as to when to conduct an initial survey of a prospective provider or supplier.

Supreme Court, U.S.
FILED

(4)
No. 98-1109
MAR 18 1999

CLERK

In the Supreme Court of the United States

OCTOBER TERM, 1998

DONNA E. SHALALA, SECRETARY OF HEALTH
AND HUMAN SERVICES, ET AL., PETITIONERS

v.

ILLINOIS COUNCIL ON LONG TERM CARE, INC.

ON PETITION FOR A WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE SEVENTH CIRCUIT

REPLY BRIEF FOR THE PETITIONERS

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In the Supreme Court of the United States**OCTOBER TERM, 1998****No. 98-1109****DONNA E. SHALALA, SECRETARY OF HEALTH
AND HUMAN SERVICES, ET AL., PETITIONERS***v.***ILLINOIS COUNCIL ON LONG TERM CARE, INC.**

**ON PETITION FOR A WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS –
FOR THE SEVENTH CIRCUIT**

REPLY BRIEF FOR THE PETITIONERS

1. Respondent agrees that the Seventh Circuit's decision in this case creates a conflict in circuit authority that warrants this Court's review. See Br. in Opp. 5 ("This case * * * presents a clear circuit conflict on a significant jurisdictional issue."). As respondent explains, "the Seventh Circuit's decision" regarding the scope of the jurisdictional bar presented by 42 U.S.C. 405(h), as incorporated in 42 U.S.C. 1395ii, "squarely conflicts with [the Sixth Circuit's decision in] *Michigan Assn. of Homes & Services for the Aging, Inc. v. Shalala*, 127 F.3d 496 [(1997)]," and with the "other court of appeals decisions that have limited the holding in *Bowen v. Michigan Academy of [Family]*

Physicians, 476 U.S. 667 (1986) * * * in light of subsequent amendments to Part B of the Medicare program." Br. in Opp. 5; see Pet. 15-16 (citing, *inter alia*, *St. Francis Medical Center v. Shalala*, 32 F.3d 805 (3d Cir. 1994), cert. denied, 514 U.S. 1016 (1995); *Abbey v. Sullivan*, 978 F.2d 37 (2d Cir. 1992); *National Kidney Patients Ass'n v. Sullivan*, 958 F.2d 1127 (D.C. Cir. 1992), cert. denied, 506 U.S. 1049 (1993); and *American Academy of Dermatology v. Department of Health & Human Services*, 118 F.3d 1495 (11th Cir. 1997)).¹

Respondent, moreover, agrees that the conflict over the scope of Section 405(h)'s jurisdictional bar on pre-enforcement challenges to Medicare regulations is "of widespread importance for both a federal agency and for providers nationwide that participate in Medicare." Br. in Opp. 6. The conflict, it notes, is likely to "spawn confusion in the lower courts," "consume an increasing amount of judicial resources," and "encourage forum shopping by plaintiffs seeking to challenge Medicare regulations." *Id.* at 6-7. Respondent therefore joins the

Secretary in urging the Court to grant the petition, and urges that the case be set for plenary review.²

2. When we filed the petition for certiorari, we suggested (Pet. 8-9, 17) that it be held pending the Court's decision in *Your Home Visiting Nurse Services, Inc. v. Shalala*, No. 97-1489 (*Your Home*), and then disposed of as appropriate in light of that decision. The Secretary's petition suggested that the Court's decision in *Your Home* might implicate issues concerning the scope of Section 405(h)'s bar and the effect of the Court's prior decision in *Bowen v. Michigan Academy of Family Physicians*, 476 U.S. 667 (1986). Although respondent agrees that this case warrants review, respondent argues in its response to the petition that the case should not be held pending decision in *Your Home*, and that plenary review should be granted.

The Court rendered its decision in *Your Home* on February 23, 1999. We now agree with respondent that the appropriate disposition of the petition is to grant plenary review. The Court's decision in *Your Home* is consistent with the Secretary's position here: that Section 405(h), as made applicable to the Medicare Act by 42 U.S.C. 1395ii, channels all claims arising under

¹ Although acknowledging a circuit conflict and agreeing that the Secretary's petition should be granted, respondent argues (Br. in Opp. 14-15) that the decision below is consistent with *United States qui tam Body v. Blue Cross & Blue Shield of Alabama, Inc.*, 156 F.3d 1098 (11th Cir. 1998). That case, however, involved a *qui tam* suit brought under the False Claims Act, 31 U.S.C. 3729, to recover allegedly wrongful payments made to a Medicare provider. The case did not involve claims against the government and, as the court of appeals held, the *qui tam* relator's cause of action and substantive rights arose under the False Claims Act, not the Medicare statute. 156 F.3d at 1105. As a result, that decision turns on claims and issues that differ substantially from those presented in this case.

² As explained in the petition, the Secretary challenges the judgment of the court of appeals only insofar as it reinstates respondent's claims with respect to, and on behalf of, its members that participate in the Medicare program. See Pet. 7 n.5; see also Pet. i (limiting question presented to whether facilities participating "in the Medicare program" may obtain judicial review under 28 U.S.C. 1331 and 1346 "to challenge the validity of Medicare regulations") (emphasis added). Medicaid (unlike Medicare) does not incorporate the jurisdictional limitation of Section 405(h); as a result, Section 405(h) does not apply to respondent's claims arising under, and on behalf of members participating in, the Medicaid program. Pet. 7 n.5.

the Medicare Program to the avenues of administrative and judicial review provided by the Medicare Act itself—here, as provided by Section 405(g), which is made applicable in this case by 42 U.S.C. 1395cc(h)(1). *Your Home*, however, does not discuss *Michigan Academy*. See Pet. 13-14. Nor does it address the relationship of *Michigan Academy* to *Heckler v. Ringer*, 466 U.S. 602 (1984), which rejected the contention that Section 405(h)'s jurisdictional bar does not extend to challenges that, like respondent's claim here, do not themselves involve a specific claim for benefits. See Pet. 12. Because the court of appeals expressed the view that this Court's decision in *Michigan Academy* compelled it to reject the Secretary's position in this case despite the Secretary's reliance on *Ringer*—and expressly stated that it was "obliged to follow the holding of *Michigan Academy*" unless "the Supreme Court tells [it] that * * * a change of direction" is required, Pet. App. 7a—we see no reason to remand this case for further consideration in light of *Your Home*, which does not discuss *Michigan Academy*. Accordingly, we agree with respondent (Br. in Opp. 16) that this case is ready and suitable for the Court's review, and that a remand in light of *Your Home* is neither necessary nor appropriate.

3. Respondent's defense of the ruling below is incorrect and at odds with this Court's precedents. See Pet. 13-16.

a. Respondent begins by attempting to reconcile the decision below with this Court's decision in *Heckler v. Ringer*, 466 U.S. at 614-617. See Br. in Opp. 9-10. In *Ringer*, this Court held that, under Section 405(h), as made applicable to Medicare by 42 U.S.C. 1395ii, federal courts can obtain jurisdiction over claims "arising under" the Medicare Act only if the claimant avails

himself of the administrative and judicial review mechanisms established by the Medicare statute itself, i.e., by first presenting his claim to the Secretary and exhausting administrative remedies and then filing suit under Section 405(g), which is made applicable to the Medicare Program by 42 U.S.C. 1395cc(h)(1). According to respondent, the pre-enforcement action at issue in *Ringer*, which sought the invalidation of a Medicare rule, was not "collateral" to a claim for benefits, whereas the claims in this case are; Section 405(h), respondent appears to argue, bars pre-enforcement review only of payment-related claims. Br. in Opp. 9.

That contention is inconsistent with *Ringer* itself, which holds that the "third sentence of 42 U.S.C. § 405(h), made applicable to the Medicare Act by 42 U.S.C. § 1395ii, provides that § 405(g), to the exclusion of 28 U.S.C. § 1331, is the sole avenue for judicial review for all 'claim[s] arising under' the Medicare Act," 466 U.S. at 614-615 (emphasis added; footnote omitted). Besides, respondent's claim is inextricably entwined with payment under the Medicare Act: Compliance with the regulations it challenges is a condition of participation in Medicare, and thus controls its members' eligibility for payment under the program. See 42 U.S.C. 1395i-3(a) to (d); 42 C.F.R. 483.1-483.75; see also Pet. App. 17a (That respondent's claim is entwined with benefits eligibility is "evidenced by the relief sought," because respondent "seeks continuation of Medicare payments and reimbursement for past due payments incurred by the patients at the nursing homes."). Just as the plaintiff in *Ringer* sought to bring a pre-enforcement challenge to the Secretary's rule barring payment for the treatment he wanted, respondent here seeks to bring a pre-enforcement challenge to regulations that condition its members'

participation in Medicare (and thus payments under the program) on compliance with certain substantive and remedial requirements.³

Respondent's construction is also inconsistent with the structure of the statute and the channeling function that 42 U.S.C. 405(g) and (h) are designed to serve. Section 405(g), which provides for review only of the "final decision" of the Secretary, provides jurisdiction over claims like respondent's after those claims are presented to the Secretary and administrative remedies are exhausted. Section 405(h), made applicable by 42

³ Even if one were to assume *arguendo* that respondent's claims were in some sense "collateral," that would not be sufficient to permit a federal court to assume subject matter jurisdiction. First, any collaterality exception could excuse (at most) compliance with waivable requirements of the Medicare Act's judicial review scheme; it could not permit a litigant to circumvent the non-waivable requirement that a claim be presented to the Secretary before judicial review may be had. See *Ringer*, 466 U.S. at 617-618; *Mathews v. Eldridge*, 424 U.S. 319, 328 (1976). In this case, the district court held that respondent had failed to present its claims to the Secretary, Pet. App. 19a, and respondent does not contend otherwise. Second, even if the requirement of presentation could be waived, that waiver would not be available absent a showing that following the ordinary statutory review scheme (*i.e.*, presenting claims to the Secretary and exhausting administrative remedies) would prevent the complainant from obtaining effective relief. See *Ringer*, 466 U.S. at 618 (requiring a "colorable showing that [the plaintiff's] injury could not be remedied * * * after exhaustion of his administrative remedies"); *Bowen v. City of New York*, 476 U.S. 467, 483 (1986) (permitting waiver of exhaustion where plaintiff would be "irreparably injured"). Because respondent's members in fact can obtain review after presenting their claims to the Secretary, see note 4, *infra*, respondent cannot make that showing here. See also Cross-Resp. Br. in Opp. at 11-13, 17-18 & n.10, *Illinois Council on Long Term Care, Inc. v. Shalala*, No. 98-1307.

U.S.C. 1395ii, precludes claimants from evading those presentment and exhaustion requirements by seeking review under 28 U.S.C. 1331. See *Ringer*, 466 U.S. at 614-615 ("42 U.S.C. § 405(h) * * * provides that § 405(g), to the exclusion of 28 U.S.C. § 1331, is the sole avenue for judicial review") (footnote omitted). Given the proximity of those provisions and their obviously related purposes, Section 405(h) should be read (at a minimum) as barring courts from reviewing under 28 U.S.C. 1331 and 1346 all claims that—like respondent's—can be reviewed through the mechanism established by Section 405(g); any other construction would permit providers to evade the presentment and exhaustion requirements for certain claims by seeking immediate review under 28 U.S.C. 1331 and 1346, rather than using the specific review mechanism that Congress prescribed.

Section 10(b) of the Administrative Procedure Act (APA), 5 U.S.C. 703, has a channeling function that reinforces this interpretation of Section 405(g) and (h). It expressly provides that, where Congress has provided a "special statutory review proceeding relevant to the subject matter," complainants must use that "form of proceeding for judicial review," unless it is "inadequa[te]." 5 U.S.C. 703. And the APA specifically bars resort to its general provisions for judicial review of agency action unless "there is no other adequate remedy in a court." 5 U.S.C. 704. Because respondent's members can avail themselves of the fully adequate mechanism for judicial review under 42 U.S.C. 405(g), the APA both remits them to that mechanism, and bars them from evading its prerequisites by seeking immediate review under 28 U.S.C. 1331 and 1346 and the cause of action codified in the APA.

b. Nor is respondent correct to assert (Br. in Opp. 10-12) that this Court should follow *Michigan Academy* rather than *Ringer* because it is “more recent,” and because portions of it have been followed in other decisions of this Court. In this Court’s most recent decision in the area, *Your Home*, the provider made a similar argument, seeking to avoid the jurisdictional limitations of Section 405(h) and invoking *Michigan Academy* on the ground that, absent review through 28 U.S.C. 1331, no judicial review could be had at all. See Pet. Br. at 19-20, 23, *Your Home Visiting Nurse Servs., Inc. v. Shalala*, No. 97-1489. Citing *Ringer*, this Court rejected that argument, holding the provider’s claim to be barred by Section 405(h) because the provider’s standing and the substantive basis of its claim were based on the Medicare Act. *Your Home Visiting Nurse Servs., Inc. v. Shalala*, No. 97-1489 (Feb. 23, 1999), slip op. 7. The same argument applies here with greater force, since respondent’s members do have an alternative mechanism for obtaining judicial review of the agency action they seek to challenge.⁴

⁴ Respondent attempts to distinguish *Your Home* by noting that the provider’s claim in that case did not involve a facial challenge to the validity of a regulation, and by asserting that the *Your Home* provider could avail itself of administrative remedies. Br. in Opp. 7-8. Both of those contentions are without merit. First, *Your Home* turned on whether standing and the substantive basis of the claim were founded on the Medicare Act; nothing in the decision suggests that a different result would obtain where the provider is challenging the facial validity of a Medicare regulation.

Second, this case cannot be distinguished from *Your Home* based on supposed differences in the availability of administrative remedies. Contrary to respondent’s contentions, and as we have shown in the petition (at 3-4), respondent’s nursing home members have substantial rights to administrative and judicial review of

c. Finally, respondent errs in asserting that the decision below correctly applies this Court’s decisions in *Michigan Academy* and *McNary v. Haitian Refugee Center, Inc.*, 498 U.S. 479 (1991). As explained in our petition (at 13-14), both *Michigan Academy* and *McNary* underscore the point that federal courts may assert jurisdiction over claims arising under the Medicare Act under 28 U.S.C. 1331 and 1346 only where (if at all) the statute otherwise would afford no meaningful avenue of judicial review, as only in that situation does the presumption against unreviewability come into play. See *Michigan Academy*, 476 U.S. at 678-681; *McNary*, 498 U.S. at 498. Indeed, the Court reiterated that distinction in *Thunder Basin Coal Co. v. Reich*, 510 U.S. 200 (1994), upon which respondent relies (Br. in Opp. 12-13, 14). Notwithstanding *Michigan Academy*, the Court in *Thunder Basin* held that the pre-enforcement challenge there was not subject to judicial review under 28 U.S.C. 1331 because the statutory scheme provided for meaningful judicial review after a final agency decision and evidenced an intent to allocate initial review to an administrative tribunal.

administrative actions taken to enforce federal standards of care. It is true that the administrative process will not generally address challenges to the validity of a federal regulation, but judicial review of such claims is fully available after exhaustion of administrative remedies, compilation of an administrative record detailing the factual context of the claim, and issuance of a final agency decision. The Court made that very point in *Weinberger v. Salfi*, 422 U.S. 749, 760-762 (1975), where it held that a challenge to the constitutionality of a provision of the Act—which likewise could not be resolved in the administrative process—had to be brought under Section 405(g), rather than through an independent action invoking district court jurisdiction under 28 U.S.C. 1331. See also *Michigan Ass’n of Homes & Servs. for Aging, Inc. v. Shalala*, 127 F.3d 496, 500 (6th Cir. 1997).

See 510 U.S. at 207 & n.8, 213-214. The same is true here.

* * * * *

For the foregoing reasons, and those set forth in the petition, the petition for a writ of certiorari should be granted.

Respectfully submitted.

SETH P. WAXMAN
Solicitor General

MARCH 1999

Supreme Court, U.S.

FILED

JUL 2 1999

OFFICE OF THE CLERK

No. 98-1109

(5)

In the Supreme Court of the United States

DONNA E. SHALALA, SECRETARY OF HEALTH AND
HUMAN SERVICES, ET AL., PETITIONERS

v.

ILLINOIS COUNCIL ON LONG TERM CARE, INC.

ON WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE SEVENTH CIRCUIT

JOINT APPENDIX

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PETITION FOR WRIT OF CERTIORARI FILED: JANUARY 11, 1999
CERTIORARI GRANTED: APRIL 19, 1999

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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

No. 96 C 2953
Judge Lindberg

THE ILLINOIS COUNCIL ON LONG TERM CARE INC.,
AN ILLINOIS CORPORATION, PLAINTIFF-APPELLANT

vs.

DONNA E. SHALALA, SECRETARY OF THE UNITED
STATES DEPARTMENT OF HEALTH AND HUMAN
SERVICES, ANTHONY J. TIRONE, IN HIS CAPACITY
AS DEPUTY DIRECTOR OF THE UNITED STATES
OFFICE OF SURVEY AND CERTIFICATION, HEALTH
STANDARDS AND QUALITY BUREAU, HEALTH CARE
FINANCING ADMINISTRATION; AND JOHN R. LUMPKIN
M.D., AS DIRECTOR OF THE ILLINOIS
DEPARTMENT OF PUBLIC HEALTH,
DEFENDANTS-APPELLEES

DOCKET ENTRIES

DATE	DOCKET NUMBERS	PROCEEDINGS
5/17/96	1	COMPLAINT - Civil cover sheet - Appearance(s) of Brian E. Neuffer, Dan K. Webb, John Norman Walker, Charles Paul

<u>DATE</u>	<u>DOCKET NUMBERS</u>	<u>PROCEEDINGS</u>
		Sheets, Neil E. Holmen as attorney(s) for plaintiff with Rule 39 affidavits (FIVE ORIGINAL summons(es) issued.) (Documents: 1-1 through 1-9) (dk) [Entry date 05/20/96] * * * * *
6/12/96	8	AMENDED COMPLAINT [1-1] by plaintiff (Exhibits). (dk) [Entry date 06/13/96] * * * * *
7/30/96	12	MOTION by federal defendants to dismiss or, in the alternative, for summary judgment (Attachment). (dk) [Entry date 08/05/96]
8/1/96	13	STATEMENT of material facts as to which there is no genuine issues by defendants (dk) [Entry date 08/05/96]
8/1/96	14	BRIEF by federal defendants in support of motion to dismiss [13-1], or, in the alternative, for summary judgment [13-2] (Exhibits). (dk) [Entry date 08/05/96]

<u>DATE</u>	<u>DOCKET NUMBERS</u>	<u>PROCEEDINGS</u>
8/1/96	15	MINUTE ORDER of 8/1/96 by Hon. George W. Lindberg: Response to federal defendants' motion to dismiss [13-1], or in the alternative, for summary judgment due 08/23/96 [13-2]. Reply due 08/30/96. Federal defendants' motion to file a brief in excess of 15 pages [11-1] is granted. Ruling set for 09/26/96 at 9:30 a.m. Mailed notice (dk) [Entry date 08/05/96] * * * * *
8/14/96	19	MOTION by plaintiff for preliminary injunction. (dk) [Entry date 08/15/96] * * * * *
10/4/96	24	MEMORANDUM by plaintiff in support of motion for preliminary injunction [19-1] with opposition (Exhibits). (dk) [Entry date 10/07/96]
10/4/96	24	OPPOSITION by plaintiff to motion to dismiss [13-1], or in the alternative for for summary judgment [13-2] with memorandum (Exhibits). (dk) [Entry date 10/07/96]

<u>DATE</u>	<u>DOCKET NUMBERS</u>	<u>PROCEEDINGS</u>
10/4/96	25	RESPONSE to Federal defendant's statement of material facts to which there is no genuine dispute by plaintiff (Exhibits). (dk) [Entry date 10/07/96] * * * * *
10/22/96	26	AMICUS CURIAE BRIEF by Amer Hlth Care Assn in opposition to defendants' motion to dismiss [13-1], or in the alternative, for summary judgment [13-2] (dk) [Entry date 10/24/96] * * * * *
11/8/96	29	REPLY by defendants to plaintiff's opposition to federal defendants' motion to dismiss [13-1] with motion. (dk) [Entry date 11/19/96]
11/8/96	30	BRIEF by defendant in opposition to plaintiff's motion for preliminary injunction [19-1] with reply (Attachments). (dk) [Entry date 11/19/96]
11/8/96	30	REPLY by defendants to plaintiff's opposition to federal defendants' motion to dismiss [13-1]

<u>DATE</u>	<u>DOCKET NUMBERS</u>	<u>PROCEEDINGS</u>
		with brief (Attachments). (dk) [Entry date 11/19/96]
11/8/96	31	REPLY by federal defendants to plaintiff's response to federal defendants' statement of material facts to which there is no genuine dispute [25-1]. (dk) [Entry date 11/19/96]
11/8/96	32	MOTION by unknown Natl Citizens to file an amicus brief; Notice of motion and proof of service. (dk) [Entry date 11/19/96]
11/18/96	33	MINUTE ORDER of 11/18/96 by Hon. George W. Lindberg: Motion of the National Citizens' Coalition for Nursing Home Reform to file an amicus brief [32-1] is granted. * * * [Entry date 11/19/96]
11/18/96	34	BRIEF amicus curiae by The National Citizens' Coalition for Nursing Home Reform (Exhibits). (dk) [Entry date 11/19/96]

* * * * *

<u>DATE</u>	<u>DOCKET NUMBERS</u>	<u>PROCEEDINGS</u>
12/6/96	37	REPLY memorandum by plaintiff in support of its motion for preliminary injunction [19-1] (Attachment). (dk) [Entry date 12/09/96]
1/8/97	-	SCHEDULE set on 1/8/97 by Hon. George W. Lindberg: Oral argument on defendant's motion to dismiss and the motion for preliminary injunction set for January 31, 1997 at 10:30 a.m. Mailed notice (sab)
		* * * * *
3/28/97	40	MEMORANDUM AND ORDER (dk) [Entry date 03/31/97]
3/28/97	41	MINUTE ORDER of 3/28/97 by Hon. George W. Lindberg: Defendants' motion to dismiss [13-1] is granted. Defendants' motion for summary judgment [13-2] is denied as moot. Plaintiff's motion for preliminary injunction [19-1] is denied as moot. Motion for summary judgment [27-2] is moot. Enter memorandum and order terminating case. Mailed notice (dk) [Entry date 03/31/97]

<u>DATE</u>	<u>DOCKET NUMBERS</u>	<u>PROCEEDINGS</u>
3/28/97	42	ENTERED JUDGMENT (dk) [Entry date 03/31/97]
5/23/97	43	TRANSCRIPT of proceedings for the following date(s): 01/31/97 Before Honorable George W. Lindberg (eav) [Entry date 05/27/97]
5/27/97	44	NOTICE OF APPEAL by plaintiff IL Coun Long Term from judgment entered [42-1], from Scheduling order terminating case [41-1], from motion minute order [41-2], from order [40-1] (\$105.00 Paid) (cmf) [Entry date 05/30/97]
5/27/97	45	DOCKETING STATEMENT by plaintiff IL Coun Long Term regarding appeal [44-1]. (cmf) [Entry date 05/30/97]
5/30/97	-	TRANSMITTED to the 7th Circuit the short record on appeal. Mailed notice to all counsel. (cmf)
6/9/97	-	TRANSMITTED to the 7th Circuit the long record on

<u>DATE</u>	<u>DOCKET NUMBERS</u>	<u>PROCEEDINGS</u>
		appeal no. consisting one volume of pleading , two volumes of loose pleadings (item # 1-1 & 30), three volumes of exhibits (item # 8, 14, & 24) , one volume of transcript (item # 43) of Mailed notice to all counsel. (da)
6/24/97	46	SEVENTH CIRCUIT transcript information sheet by plaintiff (eav) [Entry date 06/25/97]
8/18/98	47	CERTIFIED copy of Order from the Circuit. (97-2315); The petition for rehearing is therefore denied, and the suggestion for rehearing en banc is rejected. (ip) [Entry date 08/25/98]
8/21/98	48	CERTIFIED copy of Order from the Circuit. (97-2315); The petition for rehearing is therefore denied, and the suggestion for rehearing en banc is rejected. (ip) [Entry date 08/26/98]
8/21/98	49	CERTIFIED COPY of order from the 7th Circuit: Remanding the matter back to District Court [Appeal [44-1].

<u>DATE</u>	<u>DOCKET NUMBERS</u>	<u>PROCEEDINGS</u>
		(97-2315) (ip) [Entry date 08/26/98]
8/21/98	50	OPINION from the 7th Circuit: Argued 12/5/97; Decided 5/8/98. (97-2315) (ip) [Entry date 08/26/98]
8/21/98	51	LETTER from the 7th Circuit: Retaining record on appeal no. 97-2315 consisting of 1 volume of pleadings, 2 loose pleadings, 1 volume transcripts and volume of exhibits (Attachments) (ip) [Entry date 08/26/98]
9/4/98	52 -	LETTER from the 7th Circuit returning the record on appeal no. 97-2315 consisting of 1 volume of pleadings, 2 loose pleadings, 1 volume of transcripts and 3 volumes of exhibits (eav) [Entry date 09/08/98]
		* * * * *
4/28/99	-	SCHEDULE set on 4/28/99 by Hon. George W. Lindberg: Status hearing held and continued to April 27, 2000 at 9:30a.m. No notice (sab) -

UNITED STATES COURT OF APPEALS FOR
THE SEVENTH CIRCUIT

No. 97-2315

THE ILLINOIS COUNCIL ON LONG TERM CARE INC.,
AN ILLINOIS CORPORATION, PLAINTIFF-APPELLANT

vs.

DONNA E. SHALALA, SECRETARY OF THE UNITED
STATES DEPARTMENT OF HEALTH AND HUMAN
SERVICES, ANTHONY J. TIRONE, IN HIS CAPACITY
AS DEPUTY DIRECTOR OF THE UNITED STATES
OFFICE OF SURVEY AND CERTIFICATION, HEALTH
STANDARDS AND QUALITY BUREAU, HEALTH CARE
FINANCING ADMINISTRATION; AND JOHN R. LUMPKIN,
AS DIRECTOR OF THE ILLINOIS
DEPARTMENT OF PUBLIC HEALTH, DEFENDANTS-
APPELLEES

GENERAL DOCKET ENTRIES

DATE	PROCEEDINGS
6/2/97	U.S. civil case docketed. [97-2315] [954320-1] Transcript information sheet due 6/12/97. Appellant's brief due 7/14/97 for IL Council Long Term. (dorh)
6/2/97	[97-2315] ROA from No. Dist. of Il., E. Div. due 6/10/97. (dorh)

DATE	PROCEEDINGS
6/2/97	Filed Appellant IL Council Long Term docketing statement. [97-2315] [954344-1] (dorh)
6/11/97	Original record on appeal filed. Contents of record: 1 vol. pleadings; 1 vol. transcripts; 2 vol. loose pleadings; 3 vol. exhibits; . [97-2315] [956310-1] (fran)
* * * * *	
8/6/97	Filed 15c appellant's brief by IL Council Long Term. Disk filed. [97-2315] [974729-1] (kell)
8/6/97	Added attorney Pamela Small per appear- ance form. Appearance form filed for Notice- Only by attorney Pamela B. Small, Malcolm J. Harkins. [97-2315] [954320-1] (jenp)
* * * * *	
8/6/97	Filed 15c amicus brief by Amicus Curiae American Health Care, per order. Disk filed. [97-2315] [977449-1] (heid)
* * * * *	
9/24/97	Filed 15c appellees' brief by Donna E. Shalala and Anthony J. Tirone. Disk filed. [97-2315] [990838-1] (heid)

DATE	PROCEEDINGS
9/24/97	Filed 15c appellee's brief by John R. Lumpkin. Certification filed. [97-2315] [991472-1] (heid)
10/8/97	Filed 15c appellant's reply brief by IL Council Long Term. Disk filed. [97-2315] [995602-1] (heid)
10/10/97	Filed Appellant IL Council Long Term Citation of Additional Authority, per CR 28(j). [97-2315] [996419-1] (joce)
10/17/97	ORDER: Argument set for Friday, December 5, 1997 at 9:30 a.m. 20 minutes to appellants, 10 minutes to Illinois, 10 minutes to USA. [97-2315] [997483-1] (broo)
12/5/97	Case heard and taken under advisement by panel: Circuit Judge Frank H. Easterbrook, Circuit Judge Diane P. Wood, Circuit Judge Terence T. Evans. [97-2315] [1013435-1] (broo)
12/5/97	Case argued by James C. O'Connell for Appellee John R. Lumpkin, Jeffrey Clair for Appellee Anthony J. Tirone, Appellee Donna E. Shalala, Brian E. Neuffer for Appellant IL Council Long Term. [97-2315] [954320-1] (broo)

DATE	PROCEEDINGS
12/9/97	Attorney Brian E. Neuffer added for Appellant IL Council Long Term for purposes of oral argument. [97-2315] (broo)
1/26/98	Filed Appellee Donna E. Shalala, Appellee Anthony J. Tirone Citation of Additional Authority, per CR 28(e). Dist. [97-2315] [1027349-1] (land)
5/8/98	Filed opinion of the court by Easterbrook. VACATED and REMANDED for further proceedings. Circuit Judge Frank H. Easterbrook, Circuit Judge Diane P. Wood, Circuit Judge Terence T. Evans. [97-2315] [954320-1] (orac)
5/8/98	ORDER: Final judgment filed per opinion. With costs: n. [97-2315] [1060445-1] (orac)
6/22/98	Filed 30c Petition for Rehearing with Suggestion for Rehearing Enbanc by Appellee Donna E. Shalala, Appellee Anthony J. Tirone, Appellee John R. Lumpkin. Dist. [97-2315] [1074089-1] (kell)
6/29/98	Sent clerk's copy of request to Appellant IL Council Long Term requesting 30c of their Answer to the Petition for Rehearing with Suggestion for Rehearing Enbanc filed by the Appellees on 6/22/98. [97-2315] [1076077-

DATE	PROCEEDINGS
	1] Answer to Petition for Enbanc Rehearing due 7/13/98 for IL Council Long Term. (jame)
7/13/98	Filed 30c Answer of Appellant IL Council Long Term to Petition for Rehearing with Suggestion for Rehearing Enbanc. Dist. [97-2315] [1080284-1] (kell)
8/13/98	ORDER: Appellee Donna E. Shalala, Appellee Anthony J. Tirone, Appellee John R. Lumpkin Petition for Rehearing with Suggestion for Rehearing Enbanc is DENIED. Judge Flaum did not participate in the consideration of the suggestion for rehearing en banc. Judges Ripple, Manion and Rovner voted to grant rehearing en banc. [97-2315] [1074089-1] (kell)
8/21/98	MANDATE ISSUED. Record on appeal to be returned later. (Contents to be returned: 1 vol. pleadings; 2 vol. loose pleadings; 1 vol. transcripts; 3 vol. exhibits;.) [97-2315] [954320-1] (bobi)
8/25/98	Filed mandate receipt. [97-2315] [1093733-1] (fran)
9/3/98	Original record returned to the District Court. (Contents returned: 1 vol. pleadings; 2 vol. loose pleadings; 1 vol. transcripts; 3 vol. exhibits;) [97-2315] [954320-1] (odea)

DATE	PROCEEDINGS
9/28/98	Filed record receipt. [1103721-1] [97-2315] (fran)
11/9/98	Notice from the Supreme Court that a motion for extension of time to file a Petition for Writ of Certiorari has been GRANTED, extending such time to 12/12/98. [954320-1] [97-2315] (land)
12/8/98	Notice from the Supreme Court that a motion for extension of time to file a Petition for Writ of Certiorari has been GRANTED, extending such time to 1/10/99. [954320-1] [97-2315] (heid)
1/15/99	Filed notice from the Supreme Court of the filing of a Petition for Writ of Certiorari. Supreme Court Case No.: 98-1109. [97-2315] [1138109-1] (jame)
4/22/99	Filed order from the Supreme Court GRANTING the Petition for Writ of Certiorari. Supreme Court Case No.: 98-1109. [97-2315] [1170690-1] (heid)
4/22/99	Filed order from the Supreme Court DENYING the Petition for Writ of Certiorari. Supreme Court Case No.: 98-1307. [97-2315] [1171109-1] (squid)

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

No. 96 C 2953
Judge Lindberg

THE ILLINOIS COUNCIL ON LONG TERM CARE INC.,
AN ILLINOIS CORPORATION, PLAINTIFF

vs.

DONNA E. SHALALA, SECRETARY OF THE UNITED
STATES DEPARTMENT OF HEALTH AND HUMAN
SERVICES, ANTHONY J. TIRONE, IN HIS CAPACITY
AS DEPUTY DIRECTOR OF THE UNITED STATES
OFFICE OF SURVEY AND CERTIFICATION, HEALTH
STANDARDS AND QUALITY BUREAU, HEALTH CARE
FINANCING ADMINISTRATION; AND JOHN R. LUMPKIN
M.D., AS DIRECTOR OF THE ILLINOIS
DEPARTMENT OF PUBLIC HEALTH, DEFENDANTS

AMENDED COMPLAINT

Plaintiff, The Illinois Council on Long-Term Care, complains against Defendant Donna E. Shalala, Secretary of the United States Department of Health and Human Resources ("HHS"), Defendant Anthony J. Tirone, Deputy Director of the United States Office of Survey and Certification, Health Standards and Quality Bureau, Health Care Financing Administration ("HCFA"), and Defendant John R. Lumpkin M.D., Director of the Illinois Department of Public Health ("IDPH"), as follows:

NATURE OF THE ACTION

1. In this case, Plaintiff does not seek to overturn or modify the new health, safety, and resident rights standards established by the Omnibus Budget Reconciliation Act of 1987 ("OBRA 87"), known as the "Requirements of Participation" pertaining to the Medicaid and Medicare Programs. Indeed, Plaintiff's members have been surveyed for compliance with the Requirements of Participation since their promulgation in November, 1990, and only about 6% of them have been found out of compliance.

2. Plaintiff seeks, on behalf of its members participating in Medicaid (Counts I-III) and those participating in Medicare (Counts IV-VII), declaratory and injunctive relief, pursuant to the Federal Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. The relief sought is only against the use of certain unconstitutionally vague HCFA enforcement regulations which took effect on July 1, 1995 (the "1995 Regulations"), and certain standards and protocols informally promulgated thereunder in Transmittals 273 and 274, State Operations Manual (the "SOM"). The 1995 Regulations and the SOM have permitted arbitrary and inconsistent enforcement of the Requirements of Participation by Defendants, while simultaneously immunizing their actions from meaningful challenge by Plaintiff's members, in violation of due process of law. As a result of Defendants' conduct, the proportion of Plaintiff's members found to be out of compliance with the Requirements of Participation has soared from 6% to over 70% in the last ten months, even though the underlying Requirements of Participation have not changed.

3. Plaintiff seeks a declaratory judgment to the effect that:

A. The enforcement regulations promulgated by HCFA, which became effective on July 1, 1995 (the "1995 Regulations"), the SOM, and the various informal modifications thereof violate the Administrative Procedure Act in that they deviate from and exceed the mandate of the Omnibus Budget Reconciliation Act of 1987 ("OBRA '87") and, in the case of the SOM and informal modifications, were promulgated without the required notice and comment procedures required by the Administrative Procedures Act for substantive regulations;

B. The 1995 Regulations and the SOM are too vague and leave too many terms undefined to permit Plaintiff's members fair warning as to what conduct is proscribed and to permit surveyors sufficient guidance to fairly and consistently assess the compliance of nursing facilities;

C. The 1995 Regulations and the SOM have been inconsistently enforced, in violation of the Social Security Act;

D. The administrative review procedures provided under the 1995 Regulations violate Plaintiff's members' rights to procedural due process, because: (1) they are not permitted a pre-deprivation hearing before the imposition of even the most severe remedies such as termination, only a post deprivation hearing that can occur months after deprivation; (2) the Plaintiff's members are prohibited from contesting the crucial "scope"

and "severity" assessments of the surveyors in any post-deprivation hearings that are provided; and (3) the regulatory scheme is designed to provide Plaintiff's members with less and less process as termination approaches.

E. The remedies mandated by the regulations expose Plaintiff's members to actual and threatened irreparable harm in violation of their statutory rights and their constitutional rights to due process of law.

4. Plaintiff also seeks, first preliminarily and then permanently, an injunction against Defendants from enforcing the 1995 Regulations or the SOM against any of Plaintiff's nursing facility members.

PARTIES

5. Plaintiff is a not-for-profit trade association, duly organized and existing under the Illinois Not For Profit Corporation Act. Plaintiff's membership is comprised of more than 180 nursing facilities in Illinois.

6. Approximately 75 of Plaintiffs' members participate in only the Medicaid program, and not Medicare (hereafter "Medicaid-Only" members). Under the Medicaid program, Plaintiffs' members provide long term care to approximately 24,000 indigent persons pursuant to provider agreements with the Illinois Department of Public Aid ("IDPA"). The Plaintiff's claims on behalf of its Medicaid-Only members are set forth in Counts I-III below. Plaintiffs' remaining members (approximately 105) participate jointly in Medicare and Medicaid (hereafter "Medicare" members). Under the Medicare program, these members provide long

term care to approximately 5,000 aged persons pursuant to provider agreements with the Defendant Secretary of HHS. The Plaintiff's claims on behalf of the Medicare members are set forth in Counts IV-VII below.

7. Each of Plaintiff's members either has been or will be inspected, or "surveyed", for certification to continue under their provider agreements by Defendant IDPH, pursuant to the 1995 Regulations and the SOM. Plaintiff therefore has standing to bring this action because each of its individual members would have such standing, the interests Plaintiff seeks to protect are related to its organizational goals, and the claims asserted do not require the participation of each of its members.

8. Defendant Donna E. Shalala is the Secretary of HHS. HHS is responsible for the administration of the Medicare program under Title XVIII of the Social Security Act and the Medicaid program under Title XIX of the Social Security Act. Defendant, as the Secretary of HHS, promulgated the 1995 Regulations.

9. Defendant Anthony J. Tirone is the Deputy Director of HCFA. HCFA has the direct responsibility for supervising the implementation of the Medicare and Medicaid programs. HCFA issued the SOM, and supervises the implementation of the 1995 Regulations and the SOM.

10. Defendant John R. Lumpkin M.D. is the Director of IDPH. IDPH is responsible for applying the 1995 Regulations and the SOM to nursing facilities in Illinois.

SUBJECT MATTER JURISDICTION AND VENUE REGARDING CLAIMS ON BEHALF OF MEDICAID-ONLY MEMBERS

11. Plaintiff's claims on behalf of its Medicaid-Only members arise under the Fifth and Fourteenth Amendments to the United States Constitution, the provisions of the Social Security Act pertaining to Medicaid, 42 U.S.C. § 1396 *et seq.*, the Declaratory Judgment Act, 28 U.S.C. §§ 2201 *et seq.*, and the Administrative Procedure Act, 5 U.S.C. § 553 *et seq.* Plaintiff seeks declaratory judgment, as well as preliminary and permanent injunctions against the Defendants. The jurisdiction of this Court is invoked pursuant to 28 U.S.C. §§ 1331, 1346 and 2201.

12. Plaintiff's claims on behalf of its Medicaid-Only members arise out of acts undertaken and injuries suffered in this district. Venue is proper pursuant to 28 U.S.C. § 1391.

13. This Court has jurisdiction over Plaintiff's claims on behalf of its Medicaid-Only members, without regard to exhaustion of administrative remedies, because Plaintiff does not challenge the specific application of the 1995 Regulations and the SOM to any one facility, but challenges instead their lawfulness and their use to determine alleged certification deficiencies and impose enforcement penalties. Administrative review is unavailable to Plaintiff's members because the 1995 Regulations and the SOM preclude administrative review of those aspects of the 1995 Regulations and the SOM that Plaintiff alleges are unlawful.

**SUBJECT MATTER JURISDICTION AND VENUE
REGARDING CLAIMS ON BEHALF OF
MEDICARE MEMBERS**

14. Plaintiff's claims on behalf of its Medicare members arise under the Fifth and Fourteenth Amendments to the United States Constitution, the provisions of the Social Security Act pertaining to Medicare, 42 U.S.C. § 1395 *et seq.*, the Declaratory Judgment Act, 28 U.S.C. §§ 2201 *et seq.*, and the Administrative Procedure Act, 5 U.S.C. §§ 553 *et seq.* Plaintiff seeks declaratory judgment, as well as preliminary and permanent injunctions against the Defendants. The jurisdiction of this Court is invoked pursuant to 28 U.S.C. §§ 1331, 1346 and 2201.

15. Plaintiff's claims on behalf of its Medicare members arise out of acts undertaken and injuries suffered in this district. Venue is proper pursuant to 28 U.S.C. § 1391.

16. This Court has jurisdiction over Plaintiff's claims on behalf of its Medicare members, without regard to exhaustion of administrative remedies, because Plaintiff does not challenge the specific application of the 1995 Regulations and the SOM to any one facility, but challenges instead their lawfulness and their use to determine alleged certification deficiencies and impose enforcement penalties. Administrative review is unavailable to Plaintiff's members because the 1995 Regulations and the SOM specifically preclude administrative review of those aspects of the 1995 Regulations and the SOM that Plaintiff alleges are unlawful.

FACTUAL ALLEGATIONS

17. There are presently approximately 776 nursing facilities in Illinois that are certified and have provider agreements with HHS and the IDPA to provide services under the Medicare and/or Medicaid programs. These nursing facilities provide care to approximately 55,000 eligible indigent residents who are receiving Medicaid and 7,000 eligible aged residents who are receiving Medicare. These nursing facilities collectively have an investment of approximately three billion dollars (\$3,000,000,000.00) in buildings and equipment.

A. The Medicaid Program

18. The Social Security Act provides for health care services for individuals whose income and resources are below certain amounts ("indigent persons") under the Medicaid program. 42 U.S.C. § 1396 *et seq.*

19. Under the Medicaid program, a state develops a plan in conjunction with the federal government for a system of benefits for indigent persons and, if the plan meets certain requirements, the federal government pays up to 50% of the cost of the benefits. The IDPA enters into provider agreements with nursing facilities to provide the services under Medicaid.

20. The Social Security Act establishes certain health, safety and resident rights standards, known as "Requirements of Participation", that a nursing facility must meet to be certified to enter into Medicaid provider agreements. 42 U.S.C. § 1396r(a)(3), (b)-(d). Nursing facilities that enter into provider agreements must be annually certified as meeting these same

Requirements of Participation in order to continue under their agreements. 42 U.S.C. § 1396r(b), (c).

21. The Social Security Act provides generally for surveys of nursing facilities and Medicaid provider agreements to determine whether they continue to meet the required health and safety standards. 42 U.S.C. 1396r(g). The surveys are to be conducted by a "State Survey Agency". In Illinois, the State Survey Agency is IDPH. IDPH surveys are conducted by approximately 230 IDPH employees and agents working out of nine regional offices, who are required to use "the survey methods, procedures, and forms that are prescribed by HCFA." 42 C.F.R. § 488.26(c).

22. The Social Security Act provides for the imposition of fines and other penalties, including termination of provider agreements, against nursing facilities found by the surveys to have failed to meet the Requirements of Participation. 42 U.S.C. § 1396r(g), (h). The penalties may be imposed by the State Survey Agency, IDPA, or by HHS.

23. IDPH is initially responsible for determining certification and implementing enforcement actions against most nursing facilities participating in Medicaid. HCFA and HHS retain ultimate authority for certification and enforcement actions under Medicaid.

B. The Medicare Program

24. The Social Security Act provides for health care services for individuals who are eligible for social security benefits ("aged persons") under the Medicare program. 42 U.S.C. §§ 426, 1395 *et seq.*

25. The Medicare program is administered and funded solely by the federal government, which enters directly into provider agreements with nursing facilities to provide services under the Medicare program.

26. The Social Security Act establishes certain health, safety and resident rights standards, known as "Requirements of Participation", that a nursing facility must meet to be certified to enter into Medicare provider agreements. 42 U.S.C. § 1395i-3(a)(3), (b)-(d). Nursing facilities that enter into provider agreements must be annually certified as meeting these same Requirements of Participation in order to continue under their agreements. 42 U.S.C. 1395i-3(b), (c). The standards are substantially the same for providers under both Medicare and Medicaid.

B. The Impact of OBRA '87

27. In 1987 the Social Security Act was amended by the Omnibus Budget Reconciliation Act of 1987 ("OBRA 87") in various ways, including changes in the health, safety and resident rights standards that make up the "Requirements of Participation." For enforcement of the Requirements of Participation, OBRA 87 added to the termination of provider agreements several new remedies, including: (1) civil monetary penalties ("CMPs") of up to \$10,000 per day;

(2) imposition of temporary management; (3) appointment of a state monitor; and (4) denial of payments for new admissions; (5) directed Plans of Correction; and (6) directed in-service training. 42 U.S.C. 1395i-3(h) (Medicare); 42 U.S.C. 1396r(h) (Medicaid). OBRA 87 also mandated additional sanctions such as the loss of Nurse Aid Training and Competency Evaluation Programs ("NATCEP") 42 U.S.C. § 1395i-3(f)(2)(B) (Medicare); 42 U.S.C. § 1396r(f)(2)(B) (Medicaid), and the publication of adverse survey findings, such as notices of termination. 42 U.S.C. 1395i-3(g)(5) (Medicare); 42 U.S.C. 1396r(g)(5) (Medicaid).

28. HCFA published regulations concerning the Requirements of Participation on October 1, 1990, at 42 C.F.R. 483, Subparts E & F ("the 1990 Regulations").

29. From October 1, 1990 to July 1, 1995, the new Requirements of Participation were implemented and enforced by HCFA with the pre-OBRA 87 enforcement system. During this time period the number of facilities found not to be in compliance with the OBRA 87 requirements of participation averaged only 6% per year.

C. HCFA Violated The Administrative Procedure Act In Promulgating The Survey, Certification, and Enforcement Standards Contained In The 1995 Regulations And The State Operations Manual.

30. On November 10, 1994, HCFA published the final regulations concerning the survey, certification, and enforcement provisions of OBRA '87 (the "1995 Regulations"). These regulations, codified at 42 U.S.C. 488.300 *et seq.*, took effect on July 1, 1995.

31. The 1995 Regulations deviate substantially from the "Survey and Certification" and "Enforcement" mandates of OBRA '87, located at 1395r-3(g) & (h) for Medicare, and 1396r(g) & (h) for Medicaid. In particular, the 1995 Regulations:

A. legislate a set of detailed "scope" and "severity" classifications which are not called for in the statute, and which eliminate the State's discretion in assessing nursing facility deficiencies that was conferred by the statute.

B. remove the State's discretion to implement alternative remedies that was conferred by the statute.

C. restrict the standard of "substantial compliance" beyond what was contemplated by the statute, such that it is virtually impossible for the majority of nursing facilities to achieve or maintain "substantial compliance."

32. HCFA also issued a set of "informal regulations," known as Transmittals 273 and 274, State Operations Manual (the "SOM"), that became effective on July 1, 1995. The SOM changed both the survey protocol for inspecting a nursing facility and the basis for imposition of penalties, including termination of provider agreements. See Transmittals 273 and 274, SOM, attached hereto as Exhibit A.

33. The SOM is a substantive regulation that was not formally subjected to notice and comment procedures or promulgated as formal regulations. In particular, because the 1995 regulations created "scope"

and "severity" factors but failed to define them, HCFA requires IDPH to apply the "informal" definitions contained in the SOM to determine "substantial compliance" or "substandard quality of care."

34. The SOM also deviates from what was mandated by the 1995 Regulations and the Social Security Act. The SOM creates new concepts crucial to the enforcement scheme which are not defined or even mentioned in the 1995 regulations, such as "poor performing facilities," "historically compliant" and "date certain" facilities. SOM, §7001, 7304, 7313.

35. HCFA has made substantive changes to the SOM by way of satellite communications, written question-and-answer documents, and "interpretive" memoranda, none of which have been subjected to notice and comment procedures. For example, HCFA recently issued "reinterpretations" of the requirements for determining "substantial compliance" and "poorly performing facilities" [.] See HCFA Letter, dated December 6, 1995, at Exhibit B. These changes to the SOM were applied only prospectively. On information and belief, the requirements were altered again on or about January 26, 1996.

36. In its 1995 Regulations, HCFA effectively has exceeded the mandate of the statute and the 1990 Regulations thereunder. In promulgating the SOM and other "informal" mandates to State Survey Agencies, HCFA has further modified and expanded the 1995 Regulations without providing the formal notice and opportunity to comment required by the Administrative Procedure Act.

D. The Resulting HCFA Enforcement Regulations Are Impermissibly Vague, Inconsistently Applied, and Unreasonably Strict.

37. Under HCFA's current survey procedure, surveyors must first use the SOM to determine whether the facts indicate that deficiencies exist. A deficiency is any deviation from any Requirement of Participation.

38. Upon finding deficiencies, surveyors must use the SOM to assess whether each deficiency falls into one of the following "severity" categories: (1) "immediate jeopardy to resident health or safety;" (2) "actual harm that is not immediate jeopardy;" (3) "no actual harm with a potential for more than minimal harm, but not immediate jeopardy;" and (4) "no actual harm with a potential for minimal harm."

39. Surveyors must then use the SOM assess the "scope" of the deficiency as: (1) "Isolated;" (2) "Pattern;" or (3) "Widespread."

40. After deficiencies are collected and assessed, the surveyors must make certain determinations, including: (1) whether the deficiencies constitute a lack of "substantial compliance" with the Requirements of Participation overall; (2) whether the deficiencies constitute "substandard quality of care;" and (3) whether the deficiencies constitute "immediate jeopardy" to resident health or safety.

41. In Illinois, such determinations are made by the survey team and are documented. The IDPH makes these determinations without providing the facility any input or opportunity to respond. Moreover, the under-

lying documentation is not given to or discussed in any detail with the provider at the exit interview, but is mailed after the survey team leaves (usually within 10 days).

42. The survey process is virtually unbounded by the relevant statutory provisions, which fail to define certain key terms, including "compliance," "substantial compliance," "substandard quality of care" and "immediate jeopardy."

43. The 1995 Regulations define some of these terms, but many of these definitions are too vague and imprecise to provide meaningful guidance to surveyors and the providers. For example, 42 C.F.R. § 488.301 defines:

A. "substantial compliance" as "a level of compliance with the requirements of participation such that any identified deficiencies pose no greater risk to resident health or safety than the potential for causing minimal harm." However, the term "minimal harm" is not defined;

B. "substandard quality of care" as "one or more deficiencies related to participation requirements" under the regulatory groupings entitled Resident Behavior and Facility Practices, 42 C.F.R. § 483.13, Quality of Life, 42 C.F.R. § 483.15, or Quality of Care, 42 C.F.R. § 483.25, which constitute (1) immediate jeopardy to resident health or safety, (2) a pattern of or widespread actual harm that is not immediate jeopardy, or (3) a widespread potential for more than minimal harm, but less than immediate jeopardy, with no actual harm.

44. These definitions are rendered vague in that the 1995 Regulations do not define many of the key terms contained therein, such as "actual harm," "minimal harm," "isolated," "pattern," "widespread," and the terms "actual harm that is not immediate jeopardy, and "no actual harm with a potential for minimal harm."

45. Neither the statutory provisions, the 1995 Regulations, nor the SOM provide IDPH surveyors with sufficient guidance about the method by which compliance is to be determined and remedies for non-compliance imposed.

46. Neither the statutory provisions, the 1995 Regulations nor the SOM provide Plaintiff's members with any meaningful guidance for determining whether their conduct is in "substantial compliance," or for distinguishing between deficiencies which result in a finding of "substandard quality of care," and those which trigger lesser findings and enforcement penalties. Indeed, neither HCFA nor the Secretary ever distribute the SOM to Plaintiff's members, thus giving them no notice of the requirements contained therein.

47. Additionally, the 1995 Regulations and survey procedures have been inconsistently and arbitrarily applied because of: (1) HCFA's failure to properly promulgate the SOM according to the APA; (2) HCFA's failure to improve accuracy and consistency in the application of the regulations; and (3) HCFA's frequent issuance of memoranda and letters which change policy and the definition of key terms.

48. For example, surveyors will cite a small number of findings as indicating a deficiency with a "widespread

scope," even in nursing facilities with a very large resident population. This is a result of the lack of provision of adequate guidance to surveyors in conducting a representative "sample" of the facility's residents and the lack of guidance regarding percentages of the sample needed to demonstrate a "pattern" or "widespread" scope.

49. Additionally, the "severity" factor has been inconsistently applied due to surveyors' subjective biases and their differing interpretations of what constitutes "actual harm," "more than minimal harm" and "immediate jeopardy."

50. Nationally, 73% of nursing facilities surveyed under the 1995 Regulations and the SOM have failed to meet the new perfection standards enforced thereunder since July 1, 1995. This is a marked increase from the under 6% found out of compliance with the OBRA '87 Requirements of Participation before the 1995 Regulations and the SOM took effect. See Summary of National Facility Compliance, Exhibit C.

E. Facilities Are Not Permitted Sufficient Due Process To Address The Key Difficulties Created By The Regulations.

51. Plaintiff's members are precluded from disputing factual findings at the time they are made by surveyors, because they are never given the surveyors' written findings at the time of the exit interview. As a result, they are precluded at that time from presenting the surveyors with any evidence, facts, or medical records that might correct the surveyors' findings before they are formalized.

52. Depending on the sanction or remedy imposed, the 1995 Regulations afford nursing facilities either no hearing of any kind, a "paper" hearing, or a post-deprivation hearing under 42 C.F.R. 498.

53. A finding of "substandard quality of care," pursuant to § 488.325(g) of the 1995 Regulations, requires the facility to provide IDPH with the name of the attending physician for each resident with respect to whom a finding of "substandard quality of care" has been made. IDPH is then required to notify the attending physicians of this finding, as well as the state board responsible for licensing the facility's administrator, which notification is stigmatizing to Plaintiff's members.

54. In addition, the "substandard quality of care" finding precludes a nursing facility from conducting federally approved NATCEP training programs for its nurse aides. Since nurse aides provide direct care to residents and turnover is high for such staff, the inability of a facility to provide ongoing on-site NATCEP training of new staff jeopardizes the facility's ability to train its nurse aids appropriately and to continue operations for any significant period of time.

55. Notwithstanding the hardships created by these sanctions, they are imposed without giving the facilities an opportunity for a hearing of any kind.

56. If a facility is found not to be in "substantial compliance" 90 days subsequent to a finding of "substandard quality of care," the 1995 Regulations and the SOM require that HCFA and IDPH must also impose a ban on payments for new admissions; placement of a

state monitor, or termination of the provider agreement. These remedies are imposed prior to any hearing.

57. The 1995 Regulations circumvent the facility's ability at a hearing to contest the conclusions of a survey. Instead, the facility may contest only the facts surrounding specific findings of non-compliance and the size of any civil money penalties imposed. 42 C.F.R. § 488.408(g). For example, a facility would be permitted to contest whether a resident's hair was properly combed (42 C.F.R. 483.15(a)), but would have no right to question a surveyor's equally factual conclusion that this indicates a "widespread" deficiency that poses "immediate jeopardy" to residents. 42 U.S.C. 1395i-3(h)(4) (Medicare); 42 U.S.C. 1396r(h)(5) (Medicaid); 42 C.F.R. § 488.410(a).

58. The SOM also restricts the facility's due process rights by mandating that a facility may not appeal: (1) the inconsistency of the survey team in citing deficiencies among facilities; (2) failure of the survey team to comply with a requirement of the survey process, thus destroying any assurances that the survey will be conducted in accordance with the statute. SOM, § 7212.

59. A facility may appeal only if sanctions actually are imposed. If a facility returns to substantial compliance before sanctions are imposed, no appeal is permitted, even if the facility was sanctioned with: (1) the loss of on-site Nurse Aid training (NATCEP); (2) full disclosure of stigmatizing and potentially erroneous survey findings to the public, to the State long term care ombudsman, the Illinois Department of Professional Regulation, and referring physicians; (3) the

requirement that the facility carry all prior deficiencies on its record for the next five years, where they can impact future survey procedures and aggravate sanctions that are imposed using historical trends; (4) the requirement that the facility carry the "substandard quality of care" label into its next survey, which label entails, *inter alia*, the loss of any ability to appeal the citation of even a potentially erroneous "repeat" finding during the survey.

60. In addition to the aforementioned limited post-deprivation hearing, the regulations provide for, under limited circumstances, an informal dispute resolution, or "paper hearing." In this process, the facility may contest through the mail the survey results of a standard or complaint survey, by submitting documentation to the state survey agency (IDPH) for review. As a matter of practice, any "paper hearing" requested by a facility is "adjudicated" by the same IDPH employee who reviewed the survey findings and issued the statement of deficiencies for that nursing facility in the first place. Moreover, this "adjudication" is conducted under the presumption that all the facts presented in the "paper hearing" were already presented to the surveyors during the survey, or at the exit interview. This presumption is often false due to the failure of the surveyors, under current procedures, to inform facilities of their proposed factual findings during the survey or exit interview.

61. The only sanction stayed by a facility's request for any "paper" or other hearing is the collection (but not the imposition) of civil money penalties, or CMPs. The 1995 Regulations specify, moreover, that, in considering appeals of the CMP range selected, the

presiding official must apply a "clearly erroneous" standard of review and, should any basis for the imposition of CMPs exist, may not: (1) reduce the CMP to zero; (2) review the government's exercise of discretion to impose a CMP; or (3) consider any factors other than those which HCFA and IDPH may consider. 42 U.S.C. 488.438(e). These limitations are further evidence of HCFA's attempt to legislate away the facility's due process rights through the 1995 Regulations.

62. The 1995 Regulations prescribe a limited system to contest these remedies in a full post-deprivation hearing. For Medicaid facilities, the State is required to complete this hearing within 120 days after the deprivation. 42 C.F.R. § 431.153(b).

63. On information and belief, a full post-deprivation hearing regarding Medicare termination presently does not occur until at least 6 months subsequent to the imposition of the sanction.

F. Defendants' Inconsistent And Arbitrary Enforcement Practices Under The 1995 Regulations Have Caused The Number Of Facilities Found Out Of Compliance With The Requirements Of Participation To Soar.

64. Plaintiff does not complain of the OBRA '87 Requirements of Participation themselves, but only the survey, certification and enforcement scheme implemented in the 1995 Regulations, and SOM and other "informal" interpretations of the SOM. Indeed, under 6% of facilities surveyed nationally under the enforcement scheme existing prior to promulgation of the 1995 Regulations were found to be out of substantial com-

pliance with the 1990 Requirements of Participation. See Exhibit D "Trends in Percent of Facilities With Level A Violations" (American Health Care Association Deficiency Report, September 1995).

65. Beginning July 1, 1995, nursing facilities nationwide began being surveyed pursuant to the 1995 Regulations and the SOM. As a result of this new enforcement scheme, 6,050 out of 8,711, or 73%, of the facilities surveyed nationally were found to be out of compliance, and 2,623 (30%) of those facilities were scheduled for termination. See Exhibit C.

66. Furthermore, the implementation of the 1995 Regulations and the SOM have resulted in varying results from state to state. In Illinois, 73% of facilities were found to be out of compliance. Meanwhile, in Michigan, 99% of the facilities surveyed were found to be out of compliance, Indiana's nursing facilities were 86% out of compliance, Minnesota facilities were 90% out of compliance, Ohio facilities were 87% out of compliance, and Wisconsin facilities were 80% out of compliance. See Exhibit C.

67. Of the Illinois nursing facilities surveyed to date under the new regulations and SOM, at least 22 have received notices from HHS that their providers agreements will be terminated.

68. The enforcement of the 1995 Regulations and the SOM will have a substantial impact in Illinois because, of the 90,000 nursing home beds in use in Illinois, only about 31% are financed by private pay or private insurance. The remaining 68% are subject to 1995 regulations and the SOM because they serve Medicaid

and/or Medicare patients almost exclusively, and would not exist but for Medicaid and Medicare reimbursement, having been constructed, acquired or expanded to provide care for such patients. See IDPH Long Term Care Facility Statewide Summary Profile, Exhibit E). Many of these facilities could not have received bank financing or a certificate of need if they had not been certified and entered into provider agreements with HHS and IDPA, and many of them would be rendered immediately in default on their mortgage agreements should termination of their provider agreements occur.

MEDICAID-ONLY MEMBERS' CLAIMS

COUNT I

Enforcement Regulations Are Void For Vagueness

69. Plaintiff, on behalf of its Medicaid-Only members incorporates paragraphs 1-13, 17-23, 27-68 above as though set forth specifically herein.

70. The 1995 Regulations promulgated by the Defendant Secretary of HHS which establish procedures under the Medicaid program for the survey and certification of long-term care facilities, as well as the penalties for noncompliance, as monitored and enforced by HCFA, are unconstitutionally vague in that they fail to provide an individual of ordinary intelligence a reasonable opportunity to comply with their requirements.

71. The 1995 Regulations are unconstitutionally vague as to the definition of those key factors which are used by surveyors to determine "substantial compliance" and "substandard quality of care." Specifically,

the terms "actual harm," "minimal harm," "isolated," "pattern" and "widespread" are left undefined. This forces surveyors to make *ad hoc*, subjective determinations concerning the factors which must be weighed in reaching the conclusion that a facility is not in "substantial compliance" or provides "substandard quality of care."

72. This lack of specificity has resulted in arbitrary and discriminatory enforcement of the regulations. Certain Illinois nursing facilities have been found to be in noncompliance with the certification standards, as well as providing "substandard quality of care" while others with the same types of deficiencies have been found to be in "substantial compliance." This pattern of arbitrary and discriminatory enforcement is clear when compared to the dramatically differing rates of non-compliance and "substandard quality of care" found in facilities in other states.

73. The Secretary's failure to promulgate clear regulations for the determination of deficiencies deprives the Plaintiff's Medicaid-Only members of both fair notice of the deficiencies for which they will be penalized, as well as fair enforcement of the regulations, in violation of their rights to due process under the Fifth and Fourteenth Amendments to the United States Constitution.

COUNT II**Violations Of The Administrative
Procedures Act (APA)**

74. Plaintiff, on behalf of its Medicaid-Only members incorporates paragraphs 1-10, 17-23, 27-73 above as though set forth specifically herein.

75. The 1995 Regulations and the SOM pertaining to the Medicaid program violate the Administrative Procedure Act because they promulgate substantive rules that deviate from and exceed the legislative mandate of OBRA '87 in violation of the APA. Consequently, those survey methods, procedures and forms that exceed the mandate of OBRA '87 are illegal, void and of no effect.

76. The survey methods, procedures and forms contained in the SOM, HCFA Program letters, and other informal publications applicable to the Medicaid program that Defendants have required surveyors to use are also substantive rules that should be declared illegal, void and of no effect in that:

A. they were not promulgated in accordance with the notice and comment requirements of the APA, and are otherwise contrary to law because Defendants failed to provide an adequate statement of basis and purpose of the rule, in violation of the APA. 5 U.S.C. §§ 553 *et seq.*, 706.

B. the survey methods, procedures and forms contained in these publications deviate from and exceed the mandate of OBRA '87 and the 1995 Regulations, in violation of the APA.

COUNT III**Procedural Due Process**

77. Plaintiff, on behalf of its Medicaid-Only members incorporates paragraphs 1-13, 17-23, 27-76 above as though set forth specifically herein.

78. Plaintiff's Medicaid-Only members have a protectable property interest in their participation in the Medicaid Program because:

A. The nursing facilities entered into the provider agreements in reliance on and with the expectation that HHS and IDPA would engage in the good faith performance of those agreements, such that their participation in the Medicaid program would continue from year to year, subject to reasonable regulation and enforcement of health and safety standards.

B. Over 95% of the Medicaid-Only members' beds currently in use are devoted principally to Medicaid residents, such that it would be impossible for the Plaintiff's Medicaid-Only members to convert their facilities into "private pay" facilities;

C. Most of the Plaintiff's Medicaid-Only members' beds make up 98% of their census and would not have been able to receive bank financing or a Certificate of Need absent the promise of significant Medicaid funding;

D. The Plaintiff's Medicaid-Only members are prohibited from voluntarily withdrawing from the Medi-

caid program by transferring Medicaid patients out. 42 C.F.R. § 482.12(a)(2).

79. Plaintiff's Medicaid-Only members also have a liberty interest in their reputation for quality care, which reputation is damaged by publication and dissemination to health professionals, family members and the general public of survey results and termination notices, which actions are taken without a hearing of any kind.

80. A determination that a nursing facility is not in "substantial compliance" or provides "substandard quality of care" carries with it penalties sufficiently severe that their imposition can jeopardize a facility's ability to continue operations. Yet pursuant to 42 U.S.C. § 488.408(g), a facility may not appeal the choice of remedy or the factors considered in selecting remedies.

81. In addition, the regulations provide no provision whereby a facility may challenge its designation as providing "substandard quality of care" if such facilities correct all alleged deficiencies before sanctions are imposed (as the regulations require them to do). Facilities that have thus corrected the deficiencies that resulted in the "substandard quality of care" designation by the date certain nonetheless will be considered to have provided "substandard quality of care" for the purposes of the next survey cycle. This non-appealable designation thus exposes the provider to enhanced and accelerated enforcement penalties in subsequent survey cycles.

82. After the facilities' initial survey, the regulations specify that a nursing facility may not utilize "informal dispute resolution." Therefore, nursing facilities do not have any "paper due process" to contest any deficiency that is cited in revisit surveys.

83. Due process requires that a party whose conduct is made subject to administrative action be given an opportunity to contest the validity of such action. Defendants have violated the rights of the Medicaid-Only members to due process of law under the Fifth and Fourteenth Amendments of the United States Constitution: (1) by failing to permit a challenge to a surveyor's assignment of "scope" and "severity" levels; (2) by failing to permit a challenge of the factors applied by HCFA or IDPH in determining enforcement remedies; (3) by providing no mechanism whereby "date certain" facilities can challenge a "substandard quality of care" determination; (4) by restricting the rights of facilities to contest even erroneous "repeat findings;" and (5) by limiting the ability to appeal the range of CMPs.

MEDICARE MEMBERS' CLAIMS

Count IV

Enforcement Regulations Are Void For Vagueness

84. Plaintiff, on behalf of its Medicare members incorporates paragraphs 1-10, 14-17, 24-68 above as though set forth specifically herein.

85. The 1995 Regulations promulgated by the Defendant Secretary of HHS which establish procedures under the Medicare program for the survey

and certification of long-term care facilities, as well as the penalties for noncompliance, as monitored and enforced by HCFA, are unconstitutionally vague in that they fail to provide an individual of ordinary intelligence a reasonable opportunity to comply with their requirements.

86. The 1995 Regulations are unconstitutionally vague as to the definition of those key factors which are used by surveyors to determine "substantial compliance" and "substandard quality of care." Specifically, the terms "actual harm," "minimal harm," "isolated," "pattern" and "widespread" are left undefined. This forces surveyors to make *ad hoc*, subjective determinations concerning the factors which must be weighed in reaching the conclusion that a facility is not in "substantial compliance" or provides "substandard quality of care."

87. This lack of specificity has resulted in arbitrary and discriminatory enforcement of the regulations. Certain Illinois nursing facilities have been found to be in noncompliance with the certification standards, as well as providing "substandard quality of care" while others with the same types of deficiencies have been found to be in "substantial compliance." This pattern of arbitrary and discriminatory enforcement is clear when compared to the dramatically differing rates of non-compliance and "substandard quality of care" found in facilities in other states.

88. The Secretary's failure to promulgate clear regulations for the determinations of deficiencies deprives the Plaintiff's Medicare members of both fair notice of the deficiencies for which they will be

penalized, as well as fair enforcement of the regulations, in violation of their rights to due process under the Fifth and Fourteenth Amendments to the United States Constitution.

COUNT V

Violation of Social Security Act

89. Plaintiff, on behalf of its Medicare members incorporates paragraphs 1-10, 14-17, 27-68, 84-88 above as though set forth specifically herein.

90. The applicable Medicare statute provides that HHS and IDPH "shall implement programs to measure and reduce inconsistency in the application of survey results among surveyors." 42 U.S.C. § 1395i-3(g)(2)(D). This requirement is carried over into the regulations at 42 C.F.R. § 488.312, which states: "HCFA does and the survey agency must implement programs to measure accuracy and improve consistency in the application of survey results and enforcement remedies."

91. To date neither HHS, HCFA, nor IDPH have taken adequate measures to ensure survey consistency. As a direct result, nursing facilities in Illinois are not being surveyed consistently, and have been inappropriately identified as both out of compliance and providing substandard quality of care, in violation of the Social Security Act.

COUNT VI
Violations Of The Administrative
Procedures Act (APA)

92. Plaintiff, on behalf of its Medicare members incorporates paragraphs 1-10, 14-17, 24-68, 84-91 above as though set forth specifically herein.

93. The 1995 Regulations and the SOM pertaining to the Medicare program violate the Administrative Procedure Act because they promulgate substantive rules that deviate from and exceed the legislative mandate of OBRA '87 in violation of the APA. Consequently, those survey methods, procedures and forms that exceed the mandate of OBRA '87 are illegal, void and of no effect.

94. The survey methods, procedures and forms contained in the SOM, HCFA Program letters, and other informal publications applicable to the Medicare program that Defendants have required surveyors to use are also substantive rules that because should be declared illegal, void and of no effect in that:

A. they were not promulgated in accordance with the notice and comment requirements of the APA, and are otherwise contrary to law because Defendants failed to provide an adequate statement of basis and purpose of the rule, in violation of the APA. 5 U.S.C. §§ 553 *et seq.*, 706,

B. the survey methods, procedures and forms contained in these publications deviate from and exceed the mandate of OBRA '87 and the 1995 Regulations, in violation of the APA.

COUNT VII
Procedural Due Process

95. Plaintiff, on behalf of its Medicare members incorporates paragraphs 1-10, 14-17, 24-68, 84-94 above as though set forth specifically herein.

96. Plaintiff's Medicare members have a protectable property interest in their participation in the Medicare program because:

A. The nursing facilities entered into the provider agreements in reliance on and with the expectation that HHS would engage in the good faith performance of those agreements, such that their participation in the Medicare program would continue from year to year, subject to reasonable regulation and enforcement of health and safety standards.

B. The Plaintiff's Medicare members are prohibited from voluntarily withdrawing from the Medicare program by transferring Medicare patients out. 42 C.F.R. § 483.12(a)(2).

97. Plaintiff's Medicare members also have a liberty interest in their reputation for quality care, which reputation is damaged by publication and dissemination to health professionals, family members and the general public of survey results and termination notices, which actions are taken without a hearing of any kind.

98. A determination that a nursing facility is not in "substantial compliance" or provides "substandard quality of care" carries with it penalties sufficiently severe that their imposition can jeopardize a facility's

ability to continue operations. Yet pursuant to 42 U.S.C. § 488.408(g), a facility may not appeal the choice of remedy or the factors considered in selecting remedies.

99. In addition, the regulations provide no provision whereby a facility may challenge its designation as providing "substandard quality of care" if such facilities correct all alleged deficiencies before sanctions are imposed (as the regulations require them to do). Facilities that have thus corrected the deficiencies that resulted in the "substandard quality of care" designation by the date certain nonetheless will be considered to have provided "substandard quality of care" for the purposes of the next survey cycle. This non-appealable designation thus exposes the provider to enhanced and accelerated enforcement penalties in subsequent survey cycles.

100. After the facilities' initial survey, the regulations specify that a nursing facility may not utilize "informal dispute resolution." Therefore, nursing facilities do not have any "paper due process" to contest any deficiency that is cited in revisit surveys.

101. Due process requires that a party whose conduct is made subject to administrative action be given an opportunity to contest the validity of such action. Defendants have violated the rights of the Medicare members to due process of law under the Fifth and Fourteenth Amendments of the United States Constitution: (1) by failing to permit a challenge to a surveyor's assignment of "scope" and "severity" levels; (2) by failing to permit a challenge of the factors applied by HCFA and IDPH in determining enforcement rem-

edies; (3) by providing no mechanism whereby "date certain" facilities can challenge a "substandard quality of care" determination; (4) by restricting the rights of facilities to contest even erroneous "repeat findings;" and (5) by limiting the ability to appeal the range of CMPs.

RELIEF REQUESTED ON BEHALF OF PLAINTIFF'S MEDICAID-ONLY MEMBERS

WHEREFORE, for all the above and foregoing Counts, Plaintiff respectfully requests that this Honorable Court grant it the following relief for its Medicaid-Only members:

A. Issue a judgment declaring that those factors set forth in 42 C.F.R. § 488.404 concerning the Survey and Certification of Long-Term Care Facilities pertaining to the Medicaid program are unconstitutionally vague and violate Plaintiff's Medicaid-Only members' rights to due process under the Fifth and Fourteenth Amendments to the United States Constitution;

B. Issue a judgment declaring that, by failing to promulgate survey methods, procedures and forms pursuant to public notice and comment requirements, Defendants have imposed substantive obligations on nursing facilities in violation of the Administrative Procedures Act;

C. Issue a judgment declaring that the appeal procedures provided under the regulations are inadequate, unjust, and violate Plaintiff's Medicaid-Only members' rights to procedural due process;

D. After a hearing, issue a preliminary injunction restraining the Defendants from requiring the disclosure to attending physicians and state licensing officials of survey results for any of Plaintiff's Medicaid-Only members found to have provided "substandard quality of care," until such time as Plaintiff's claims can be addressed at trial;

E. After a hearing, issue a preliminary injunction restraining Defendants from imposing or collecting civil monetary penalties from Plaintiff's members as a remedy for any deficiency until such time that Plaintiff's Medicaid-Only claims can be addressed at trial;

F. After a hearing, issue a preliminary injunction restraining Defendants from imposing upon Plaintiff's Medicaid-Only members any ban on payment as a remedy for any deficiency until such time that Plaintiff's claims can be addressed at trial;

G. After a hearing, issue a preliminary injunction restraining Defendants from interfering with any NATCEP nurse aide training and competency evaluation program conducted by Plaintiff's Medicaid-Only members following a member's citation for any deficiency which results in a finding of "substandard quality of care," until such time that Plaintiff's claims can be addressed at trial;

(a) After a trial, permanently enjoin Defendants from the actions set forth in paragraphs D through G hereto;

(b) Award Plaintiff its reasonable attorney's fees and expenses to the extent allowable under law; and

(c) Enter such other and further relief as this Honorable Court deems just and proper.

RELIEF REQUESTED ON BEHALF OF PLAINTIFF'S MEDICARE MEMBERS

WHEREFORE, for all the above and foregoing Counts, Plaintiff respectfully requests that this Honorable Court grant it the following relief for its Medicare members:

A. Issue a judgment declaring that those factors set forth at 42 C.F.R. § 488.404 concerning the Survey and Certification of Long-Term Care Facilities pertaining to the Medicare program are unconstitutionally vague and violate Plaintiff's Medicare members' rights to due process under the Fifth and Fourteenth Amendments to the United States Constitution;

B. Issue a judgment declaring that Defendants have failed to meet their obligations under federal law to ensure consistency in survey, certification and application of enforcement remedies.

C. Issue a judgment declaring that, by failing to promulgate survey methods, procedures and forms pursuant to public notice and comment requirements, Defendants have imposed substantive obligations on nursing facilities in violation of the Administrative Procedures Act;

D. Issue a judgment declaring that the appeal procedures provided under the regulations are inadequate, unjust, and violate Plaintiff's Medicare members rights to procedural due process;

E. After a hearing, issue a preliminary injunction restraining the Defendants from requiring the disclosure to attending physicians and state licensing officials of survey results for any of Plaintiff's Medicare members found to have provided "substandard quality of care," until such time as Plaintiff's claims can be addressed at trial;

F. After a hearing, issue a preliminary injunction restraining Defendants from imposing or collecting civil monetary penalties from Plaintiff's members as a remedy for any deficiency until such time that Plaintiff's Medicare claims can be addressed at trial;

G. After a hearing, issue a preliminary injunction restraining Defendants from imposing upon Plaintiff's Medicare members any ban on payment as a remedy for any deficiency until such time that Plaintiff's claims can be addressed at trial;

H. After a hearing, issue a preliminary injunction restraining Defendants from interfering with any NATCEP nurse aide training and competency evaluation program conducted by Plaintiff's Medicare members following a member's citation for any deficiency which results in a finding of "substandard quality of care," until such time that Plaintiff's claims can be addressed at trial;

(a) After a trial, permanently enjoin Defendants from the actions set forth in paragraphs E through H hereto;

(b) Award Plaintiff its reasonable attorney's fees and expenses to the extent allowable under law; and

(c) Enter such other and further relief as this Honorable Court deems just and proper.

Respectfully Submitted,

ILLINOIS COUNCIL ON LONG-TERM CARE

By /s/ NEIL E. HOLMEN
One of Its Attorneys

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[Exhibit A To Amended Complaint]
 [Excerpts]

State Operations Manual
HCFA Publication 7
Revision 273
June 1995

<u>NEW MATERIAL</u>	<u>REVISED PAGES</u>	<u>REPLACE PAGES</u>
Part 7, Table of Contents	7-1 - 7-3 (3 pp.)	—
Secs. 7000 - 7907	7-5 - 7-80 (75 pp.)	—
List of Exhibits	5-6.1 - 5-6.3 (3 pp.)	5-6.1 - 5-6-2 (2 p.)
Exhibits 139 -148	5-707 - 5.723 (16 pp.)	—

CHANGED PROCEDURES EFFECTIVE DATE: JULY 1, 1995

These procedures are effective for surveys which begin on or after July 1, 1995, to be consistent with the Survey, Certification and Enforcement Regulation for SNFs and NFs which was published in the Federal Register on November 10, 1994 and is effective on July 1, 1995.

Section 7000. Introduction. Section 7000 provides background and philosophy for the survey and enforcement procedures outlined in this part.

Section 7001. Definitions and Acronyms. Section 7001 provides definitions and acronyms used in this part.

Section 7002. Change in Certification Status for Medicaid NFs. Section 7002 instructs procedures to follow when a Medicaid NFs wishes to participate as a Medicare SNF.

Section 7004. SNFs - Citations and Description. Section 7004 describes what a SNF is and its statutory basis.

Section 7006. NFs - Citations and Description. Section 7006 describes what a NF is and its statutory basis.

Section 7008. Types of Facilities That May Qualify as SNFs and NFs. Section 7008 describes the types of facilities that may qualify as a SNF or NF.

Section 7010. SNFs Providing Outpatient Physical Therapy, Speech Pathology, or Occupational Services. Section 7010 describes the services that a SNF may provide.

Section 7014. Special Waivers Applicable to SNFs and NFs. Section 7014 describes the requirements for nursing staff waivers, life safety code waivers, and variations of patient room size and/or beds per room.

Section 7200. Emphasis, Components and Applicability. Section 7200 describes the tasks to be completed for surveying SNFs and NFs.

Section 7201. Survey Team Size and Composition - Length of Survey. Section 7201 describes the size of survey teams, qualification of surveyors, what types of surveyors should be represented on a survey team and the general length of a survey.

* * * * *

Chapter VII
**SURVEY AND ENFORCEMENT PROCESS FOR SNFs
AND NFs**

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REV. 273

Standards and Certification, June 1995

7-3

* * * * *

[7-39]

Enforcement Process**7400. ENFORCEMENT REMEDIES FOR SNFs AND NFs**

A. **Introduction.** Sections 1819(h) and 1919(h) of the Act, as well as 42 CFR 488.404, 488.406, and 488.408, provide that HCFA or the State may impose one or more remedies in addition to, or instead of, termination of the provider agreement when the State or HCFA finds that a facility has deficiencies. The remedies available to the RO, or the SMA, or both, as appropriate, are listed in subsection C.

B. **General.** OBRA 1987 mandated the elimination of the preexisting hierarchical participation requirements and their replacement with a system capable of detecting and responding to deficiencies with any participation requirement. Therefore, the new nursing home enforcement protocol/procedures are based on the premise that all requirements must be met and enforced. These requirements take on greater or lesser significance depending on the specific circumstances and resident outcomes in each facility.

A SNF, NF, or dually-participating facility (SNF/NF) will be subject to one or more enforcement remedies for noncompliance with one or more participation requirements. Each facility that has deficiencies (other than those isolated deficiencies that have been determined to constitute no actual harm with potential for only minimal harm) must submit an acceptable PoC. HCFA's requirement relative to submittal of

PoCs can be found in §2728.B. A PoC is not an enforcement remedy.

C. **Listing of Remedies.**

1. **Available Enforcement Remedies.** In accordance with 42 CFR 488.406, the following remedies are available:
 - Termination of the provider agreement;
 - Temporary management;
 - Denial of payment for all Medicare and/or Medicaid residents by HCFA;
 - Denial of payment for all new Medicare and/or Medicaid admissions;
 - CMPs;
 - State monitoring;
 - Transfer of residents;
 - Transfer of residents with closure of facility;
 - DPoC;
 - Directed in-service training; and
 - Alternative or additional State remedies approved by HCFA. [7-40]

2. **Mandatory Enforcement Remedies.** Regardless of what other remedies the SMA may want to establish in addition to the remedy of termination of the provider agreement, it must establish, at a minimum, these statutorily specified remedies or an approved alternative to these specified remedies:
 - Temporary management;
 - Denial of payment for all new admissions;
 - CMPs;
 - Transfer of residents;
 - Transfer of residents with closure of facility; and
 - State monitoring.

The SMA may establish additional or alternative remedies provided that the State has been authorized to do so under its State plan by HCFA. Guidance on the review and approval (or disapproval) of State Plan amendment requests for alternative or additional remedies can be found in §7805.

3. **Availability of SMA Remedies To RO in Dually-Participating Facilities.** Whenever a SMA's remedy is unique to its State plan and has been approved by HCFA, then that remedy may also be imposed by the RO against the Medicare provider agreement of a dually-participating facility in that State. Where HCFA has approved a State's ban on ad-

missions remedy as an alternative remedy under the State plan, HCFA may impose this remedy relative to only Medicare and Medicaid residents. Only the State can ban the admission of private pay residents.

D. **Measuring Seriousness of Deficiencies.** Measuring the seriousness of deficiencies is only for the purpose of determining the enforcement response most appropriate for specific degrees of non-compliance. The system by which the seriousness of deficiencies is rated (i.e., harm and scope factors), is a national system to be used by States and HCFA. Immediate jeopardy has historically been determined by guidance provided in Appendix Q of the Interpretive Guidelines and will continue to be determined using that guidance. Appendix P of the Interpretive Guidelines provides guidance on how to determine the seriousness of nonimmediate jeopardy deficiencies.

E. **Selection of Remedies.**

1. **Factors That Must Be Considered When Selecting Remedies.** In order to select the appropriate remedy(ies) for a facility's noncompliance, the seriousness of the deficiency(ies) must first be assessed, because specific levels of seriousness are correlated with specific categories of enforcement responses. The assessment factors that must be used to determine the seriousness of deficiencies are presented on the visual matrix which follows later in this subsection. These factors are also listed below. They relate to whether the deficiencies constitute:

- No actual harm with a potential for minimal harm;
- No actual harm with a potential for more than minimal harm but not immediate jeopardy;

[7-41]

- Actual harm that is not immediate jeopardy; or,
- Immediate jeopardy to resident health or safety.

AND, whether deficiencies:

- Are isolated;
- Constitute a pattern; or,
- Are widespread.

[7-42]

Immediate Jeopardy to Resident Health or Safety

Actual Harm that is not Immediate Jeopardy

No Actual Harm with Potential for More than Minimal Harm that is not Immediate Jeopardy

No Actual Harm with Potential for Minimal Harm

J PoC Required: Cat. 3 Optional: Cat. 1 Optional: Cat. 2	K PoC Required: Cat. 3 Optional: Cat. 1 Optional: Cat. 2	L PoC Required: Cat. 3 Optional: Cat. 1 Optional: Cat. 2
G PoC Required* Cat. 2 Optional: Cat. 1	H PoC Required* Cat. 2 Optional: Cat. 1	I PoC Required* Cat. 2 Optional: Cat. 1 Optional: Temporary Mgmt.
D PoC Required* Cat. 1 Optional: Cat. 2	E PoC Required* Cat. 1 Optional: Cat. 2	F PoC Required* Cat. 2 Optional: Cat. 2
A No PoC No Remedies Commitment to Correct Not on HCFA-2567	B PoC	C PoC

Isolated

Pattern

Widespread

Substandard quality of care: any deficiency in §4813 Resident Behavior and Facility Practices, §483.15 Quality of Life, or in §483.25, Quality of Care, that constitutes: immediate jeopardy to resident health or safety; or, a pattern of or widespread actual harm that is not immediate jeopardy; or, a widespread potential for more than minimal harm that is not immediate jeopardy, with no actual harm.

Substantial compliance

Remedy CategoriesCategory 1 (Cat.1)

Directed Plan of Correction
State Monitor; and/or
Directed In-Service Training

Category 2 (Cat. 2)

Denial of Payment for New Admissions
Denial of Payment for All Individuals;
imposed by HCFA; and/or Civil Money
Penalties: \$50-\$3,000/day

Category 3 (Cat. 3)

Temporary Management
Termination

Optional:

Civil Money Penalties
\$3,050 - \$10,000/day

Denial of payment for new admissions must be imposed when a facility is not in substantial compliance within 3 months after being found out of compliance.

Denial of Payment and State Monitoring must be imposed when a facility has been found to have provided substandard quality of care on three consecutive standard surveys.

Note: Termination may be imposed by the State or HCFA at any time when appropriate.

Following a determination of scope and severity, the SA enters on Form HCFA-2567L the letter corresponding to the box of the grid for at least any deficiency which constitutes substandard quality of care and any deficiency which drives the choice of a required remedy

category. The SA enters this letter in ID prefix tag column immediately below the tag number of the Form HCFA-2567L. Deficiencies falling in box A are recorded on Form A.

* This is required only when a decision is made to impose alternative remedies instead of or in addition to termination. [7-43]

Once the seriousness of the deficiency(ies) is determined, and the decision is made to impose remedies instead of, or in addition to, termination, the RO, or the SA, or both, as determined in accordance with §7300, must select one or more remedies from the remedy category (or a HCFA approved alternative or additional State remedy) associated with the specific level of noncompliance in accordance with the visual matrix above. The remedy category to be applied against facility noncompliance will be determined by the most serious deficiency(ies) identified, i.e., deficiencies falling into the box closest to the highest harm and scope rated box. Additional factors may be considered, including but not limited to, those provided in subsection 2.

2. **Other Factors That May Be Considered in Selecting Enforcement Remedy Within Remedy Category.** Additional factors that may be considered to assist in determining which and/or how many remedy(ies) to impose within the available remedy categories for particular levels of noncompliance, include but are not limited to:

- The relationship of one deficiency to other deficiencies to determine;
- The facility's prior history of noncompliance in general and specifically with reference to the cited deficiency(ies); and
- The likelihood that the selected remedy(ies) will achieve correction and continued compliance.

EXAMPLE: If failure to spend money is the root cause of the facility's noncompliance, then any CMP that is imposed should at least exceed the amount saved by the facility by not maintaining compliance.

3. **Requirement For Facility To Submit PoC.** Except when a facility has isolated deficiencies that constitute no actual harm with potential for no more than minimal harm, each facility that has a deficiency must submit a PoC for approval. For any PoC to be acceptable, it must address the four elements provided in §7304.B. Those facilities having isolated deficiencies that constitute no actual harm with potential for minimal harm need not submit a PoC. The RO approves PoCs for State-operated facilities and for validation surveys; the SA approves all others. The process and timetable for HCFA's approval of PoCs under the continuation of payment provision is in accordance with §7600. The requirement that providers submit a PoC can be found in §2728.B.

F. When To Select Remedy From Specific Remedy Category.

1. Category 1. Select at least one remedy from category 1 when there:

- Are isolated deficiencies that constitute no actual harm with a potential for more than minimal harm but not immediate jeopardy; or
- Is a pattern of deficiencies that constitutes no actual harm with a potential for more than minimal harm but not immediate jeopardy.

EXCEPT when the facility is in substantial compliance, one or more of the remedies in category 1 may be applied to any deficiency.

[7-44]

CATEGORY 1 remedies include:

- DPoC (see §7500);
- State monitoring (see §7504); and
- Directed in-service training (see §7502.)

NOTE: The SA as an agent of HCFA or the SMA may impose one or more category 1 remedies, as authorized by HCFA or the SMA, in accordance with §7314.

2. Category 2. Select at least one remedy from category 2 when there are:

- Widespread deficiencies that constitute no actual harm with a potential for more than minimal harm but not immediate jeopardy; or
- One or more deficiencies (regardless of scope) that constitute actual harm that is not immediate jeopardy.

EXCEPT when the facility is in substantial compliance, one or more of the remedies in category 2 may be applied to any deficiency.

NOTE: The SMA does not have the statutory authority to impose the remedy of denial of payment for all Medicare and/or Medicaid residents.

CATEGORY 2 remedies include:

- Denial of payment for all new Medicare and/or Medicaid admissions (see §7506);
- Denial of payment for all Medicare and/or Medicaid residents, imposed by the RO (see §7508); and
- CMPs of \$50 - \$3,000 per day of noncompliance. (See §7510.)

3. Selection From Category 3. Termination or temporary management, or both, must be selected when there are one or more deficiencies that constitute immediate jeopardy to resident health or safety. A CMP of \$3,050 - \$10,000 per day may be imposed in addition to the remedies of termination and/or temporary management. Temporary management is also an option when there are widespread deficiencies constituting actual harm that is not immediate jeopardy.

CATEGORY 3 remedies include:

- Temporary management (see §7550);
- Termination (see §7556); and
- CMPs of \$3,050 - \$10,000 per day of noncompliance optional, in addition to the remedies of termination and/or temporary management. (See §7510.)

NOTE: Termination may be imposed by the SMA or the RO at any time when appropriate. Transfer of residents or transfer of residents with closure of facility will be imposed by the State as appropriate.

[Exhibit B to Amended Complaint]

[Seal omitted]

Health Care
Financing Administration

DEPARTMENT OF HEALTH & HUMAN SERVICES
Memorandum

DATE: DEC 06 1995
 FROM: Deputy Bureau Director
 Survey and Certification, HSQB
 SUBJECT: Interim Revisit Policy
 TO: Associate Regional Administrators
 Division of Health Standards and Quality
 Regions I - X
 State Agency Directors

INTERIM POLICY: EFFECTIVE UPON RECEIPT

The purpose of this memorandum is to present an interim revision to the existing policy on when a State agency must conduct a revisit following a survey. We thank you for your many comments regarding criteria for revisits. We continue to analyze and plan to develop a final policy in this area after consultation with relevant parties.

It is recognized that resource limitations may not allow revisits in every instance that noncompliance is identified. Thus, it is necessary that we issue an interim policy at this time on when to conduct revisits. This policy will remain in effect until a final policy on

revisits is developed based on further analysis and consultation.

Revisits will no longer be required if the deficiency(-ies) are determined to fall into Boxes D, E, or F if there is no finding of substandard quality of care. However, a revisit may be conducted whenever you determine that a revisit is necessary, regardless of the level of deficiencies. The policy does not alleviate the responsibility for survey agencies to ensure that providers correct all deficiencies.

This interim policy revises the existing revisit policy, found at section 7317 of Transmittal No. 273, State Operations Manual. The provider would continue to be required to meet the four points for an acceptable Plan of Correction (PoC) specified in State Operations Manual, Transmittal No. 273, section 7304C. That is, the PoC must specify:

1. How corrective action will be accomplished for those residents who have been affected by the deficient practice;
2. How the facility will identify other residents having the potential to be affected by the same deficient practice;
3. What measures will be put into place or systemic changes made to ensure that the deficient practice will not recur; and
4. How the facility will monitor its corrective actions to ensure that the deficient practice is being corrected and will not recur, i.e., what program will be put into place to monitor the

continued effectiveness of the systemic changes?

If the State agency determines that the highest level of deficiency is D, E, or F and there is no finding of substandard quality of care, the State agency may, in lieu of a revisit, determine correction and compliance by accepting the facility's PoC, if it is:

1. reasonable;
2. addresses the problem; and
3. the facility submits evidence that it has monitored its corrective action as specified in the fourth requirement of the PoC.

If the survey agency subsequently as a result of a complaint or other means, determines that the facility had not corrected the problems identified by the earlier survey, the survey agency may consider that the facility is a poor performer and recommend immediate remedies.

This interim policy is intended to give relief to the States without removing facilities from their responsibility to maintain compliance. In a subsequent memorandum, we will specify a process for completing the HCFA-2567B congruent with this policy. In addition, we will be soliciting further consultations as we develop final policies in this area.

Once again, thank you for your assistance as we work together to successfully implement this process. If you have any questions, please call me, Debbie Schoenemann, or Vic Santoro at (410) 786-6763, (410) 786-6771, or (410) 786-6778, respectively.

/s/ ANTHONY J. TIRONE
ANTHONY J. TIRONE

[Exhibit C to Amended Complaint]

A) Survey Activity Summary for January 26, 1996

The report below represents cumulative totals of survey activity through the reporting date. The figures under the bold headings are exclusive of one another. For example, one State may have conducted 47 surveys since July 1 and may not have yet rendered a decision regarding compliance or enforcement on all 47 surveys. Another State may have conducted 39 surveys and rendered compliance and enforcement decisions on all.

SURVEY ACTIVITY SUMMARY	STANDARD SURVEYS	COMPLAINT SURVEYS
Surveys Completed	8711	12,640
Compliance Decisions Rendered	8353	11,345
Facilities in substantial compliance	2303 28%	8965 79%
Facilities with Level D and above deficiencies	6050 72%	2380 21%
<i>Total immediate remedies proposed</i>	235	106
<i>Total with opportunity to correct</i>	5815	2274
<i>Facilities with substandard quality of care</i>	1188 14%	352 3%
Dispute Resolution Reviewed	975	290
<i>Total affirmed</i>	451	192
<i>Total revised</i>	524	98
Facilities verified on revisit in substantial compliance	3039	770
Facilities verified on revisit NOT in substantial compliance	687	207

REMEDIES	REMEDIES PROPOSED		REMEDIES IMPOSED
	STANDARD	COMPLAINT	
<i>State monitoring</i>	677	304	106
<i>Directed Plan of Correction</i>	1155	318	125
<i>Temporary Management</i>	13	15	10
<i>Denial of Payment for New Admissions</i>	2145	607	192
<i>Denial of Payment for All Residents</i>	139	51	6
<i>Directed Inservice Training</i>	1746	617	67
<i>Civil Money Penalty</i>	2062	718	94
<i>HCFA Approved Alternative State Remedy</i>	31	5	5
<i>Transfer of Residents/Closure of the Facility</i>	0	0	1
<i>Transfer of Residents</i>	74	12	2
<i>Termination</i>	2623	1077	21

State Implementation Report 1

01/26/1996

1995 - 01/26/1996

STANDARD

Region 5	Surveys Complete	Comp					SOC	%	SQC			Int Rem Prop	Licensure Enforcement				Dispute Resolution					
		In	%	Not	%	Tot			Care	Life	Behavior		Ban	CMP	Closure	Other	Req	Rvwd	Aff	%	Rev	%
IL	613	223	36%	390	64%	613	61	10%	50	22	14	2	0	2	0	0	160	157	71	45%	86	55%
IN	262	36	14%	226	86%	262	47	18%	88	69	35	5	4	27	0	5	41	29	16	55%	13	45%
MI	208	7	3%	201	97%	208	70	34%	189	113	32	33	12	0	0	0	19	14	4	29%	10	71%
MN	131	13	10%	118	90%	131	16	12%	12	4	0	0	0	0	0	0	5	5	2	40%	3	60%
OH	457	64	14%	393	86%	457	97	21%	148	67	42	13	0	0	0	41	92	88	32	36%	56	64%
WI	216	48	23%	162	77%	210	11	5%	4	10	3	0	0	0	0	0	67	56	11	20%	45	80%
Totals	1,887	391	21%	1,490	79%	1,881	302	16%	491	285	126	53	16	29	0	46	384	349	136	39%	213	61%
Nat'l																						
Totals	8,711	2,303	28%	6,050	72%	8,353	1,188	14%	1,803	1,099	441	235	86	158	0	112	1,180	975	451	46%	524	54%

State Implementation Report 1

01/26/1996

1995 - 01/26/1996

COMPLAINT

Region §	Surveys Complete	Comp					SQC			Im Rem Prop	Licensure Enforcement				Dispute Resolution								
		In	%	Not	%	Tot	SQC	%	Care	Life	Behavior	Ban	CMP	Closure	Other	Reg	Rvwd	Aff	%	Rev	%		
IL	1,935	548	80%	387	20%	1,935	14	1%	9	3	3	2	0	0	0	0	133	133	84	63%	49	37%	
IN	496	52	28%	135	72%	187	21	11%	19	14	11	2	0	13	0	0	22	22	18	82%	4	18%	
MI	204	85	42%	119	58%	204	10	5%	10	0	4	8	1	0	0	0	9	9	5	56%	4	44%	
MN	0	0	0%	0	0%	0	0	0%	0	0	0	0	0	0	0	0	0	0	0	0%	0	0%	
OH	513	368	72 %	145	28%	513	28	5%	35	11	5	3	0	0	0	2	14	11	5	45%	6	55%	
WI	357	333	93%	24	7%	357	1	0%	1	1	0	1	0	0	0	0	4	8	5	63%	3	38%	
Totals	3,505	2,386	75%	810	25%	3,196	74	2%	74	29	23	16	1	13	0	2	182	183	117	64%	66	36%	
Nat'l																							
	Totals	12,640	8,965	79%	2,380	21%	11,345	352	3%	516	212	126	106	14	46	1	21	346	290	192	66%	98	34%

State Implementation Report 2

01/26/1996

1995 - 01/26/1996

STANDARD

Region S	Remedies											Scope And Severity											
	01	02	03	04	05	06	07	08	09	10	11	A	B	C	D	E	F	G	H	I	J	K	L
IL	1	54	0	50	14	336	231	0	0	64	16	264	383	508	568	651	189	120	51	18	4	1	14
IN	2	7	0	204	10	113	105	0	0	4	212	143	323	261	276	623	187	117	147	72	2	4	18
MI	201	0	0	30	0	0	117	0	0	0	201	104	266	184	649	665	369	335	144	115	6	3	11
MN	9	22	0	10	0	0	35	0	0	0	76	38	45	53	122	169	37	61	30	2	0	0	0
OH	137	0	0	302	0	0	2	0	0	0	421	344	292	269	878	896	450	191	142	66	1	1	3
WI	2	105	0	17	0	1	44	0	0	0	0	200	249	128	389	342	154	61	12	0	0	0	0
Totals	352	188	0	613	24	450	534	0	0	68	926	1,093	1,558	1,403	2,882	3,346	1,386	885	526	273	13	9	46
Nat'l																							
Totals	677	1,155	13	2,145	139	1,746	2,062	31	0	74	2,623	4,748	5,470	5,136	8,083	9,650	4,362	3,768	2,083	927	36	63	77

State Implementation Report 2

01/26/1996

1995 - 01/26/1996

COMPLAINT

Region S	Remedies											Scope And Severity											
	01	02	03	04	05	06	07	08	09	10	11	A	B	C	D	E	F	G	H	I	J	K	L
IL	0	28	0	31	1	263	157	0	0	0	0	71	90	64	183	98	40	112	34	1	2	2	2
IN	0	16	0	110	0	42	53	0	0	0	110	20	34	18	81	104	29	71	48	25	0	0	0
MI	107	1	0	3	0	0	45	0	0	0	113	18	5	6	59	25	8	56	5	0	4	0	0
MN	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
OH	68	0	0	69	0	0	0	0	0	0	125	46	37	28	96	79	30	50	22	17	1	1	2
WI	0	11	0	0	0	0	9	0	0	0	0	11	4	1	16	9	3	9	3	0	0	0	0
Totals	175	56	0	213	1	305	264	0	0	0	348	166	170	117	435	315	110	298	112	43	7	3	4
Nat'l																							
Totals	304	318	15	607	51	617	718	5	0	12	1,077	567	634	522	1,311	1,268	633	1,135	517	206	33	54	39

State Implementation Report 3

01/26/1996

1995 - 01/26/1996

STANDARD

Region §	<u>Revisits Conducted</u>	<u>Revisits In Compliance</u>	<u>%</u>	<u>Revisits Not in Compliance</u>	<u>%</u>	<u>Tot Comp</u>	<u>Cat 2 or 3 Remedies Recommended</u>	<u>%</u>
IL	270	200	72%	78	28%	278	30	11%
IN	153	106	68%	51	32%	157	29	18%
MI	72	30	43%	39	57%	69	12	17%
MN	31	31	100%	0	0%	31	0	0%
OH	332	283	85%	49	15%	332	48	14%
WI	113	95	82%	21	18%	116	4	3%
Totals	971	745	76%	238	24%	983	123	13%
Nat'l								
Totals	3,712	3,039	82%	687	18%	3,726	448	12%

State Implementation Report 3

01/26/1996

1995 - 01/26/1996

COMPLAINT

<u>Region 5</u>	<u>Revisits Conducted</u>	<u>Revisits In Compliance</u>	<u>%</u>	<u>Revisits Not in Compliance</u>	<u>%</u>	<u>Tot Comp</u>	<u>Cat 2 or 3 Remedies Recommended</u>	<u>%</u>
IL	73	111	83%	22	17%	133	20	15%
IN	77	39	65%	21	35%	60	9	15%
MI	0	0	0%	0	0%	0	1	0%
MN	0	0	0%	0	0%	0	0	0%
OH	75	68	93%	5	7%	73	5	7%
WI	17	14	88%	2	13%	16	1	6%
Totals	242	232	82%	50	18%	282	36	13%
Nat'l								
Totals	948	770	79%	207	21%	977	146	15%

Sheet 1

REMEDIES	REMEDIES FORMALLY IMPOSED											TOTALS	KEY
	1	2	3	4	5	6	7	8	9	10	11		
REGION I													
CT	0	0	0	0	0	0	2	0	0	0	0	2	1 State Monitoring
MA	3	1	2	4	0	1	1	0	0	0	1	13	2 Directed PoC
ME	0	1	2	2	0	1	2	0	0	0	0	8	3 Temporary Manager
NH	0	0	0	0	0	0	0	0	0	0	0	0	4 Denial of Pmt - New
RI	0	0	0	0	0	0	0	0	0	0	0	0	5 Denial of Pmt - All
VT	0	0	0	0	0	0	0	0	0	0	0	0	6 Directed Inservice
REGION II													7 CMP
NJ	0	2	0	1	0	2	4	0	0	0	0	9	8 Alt State Remedy
NY	0	0	0	3	0	0	0	0	0	0	0	3	9 Transfer/Closure
VI	0	1	0	0	0	0	0	0	0	0	0	1	10 Transfer
REGION III													11 Termination
DC	0	0	0	0	0	0	1	0	0	0	0	1	
DE	0	0	0	0	0	0	0	0	0	0	0	0	
MD	0	0	0	0	0	0	1	0	0	0	0	1	
PA	0	0	0	0	0	0	1	0	0	0	0	1	
VA	0	0	0	0	0	0	0	0	0	0	0	0	
WV	0	0	0	0	0	0	0	0	0	0	0	0	
REGION IV													
AL	0	0	0	0	0	1	1	0	0	0	1	3	
FL	0	0	0	0	0	0	10	0	0	0	11	21	
GA	1	96	0	0	0	7	0	0	0	0	0	104	
KY	1	0	0	0	1	0	2	0	0	0	0	4	
MS	0	0	0	0	5	0	8	5	1	0	0	19	
NC	0	0	0	0	0	1	3	0	0	0	0	4	
SC	1	1	0	5	0	0	1	0	0	0	3	11	
TN	1	0	0	0	0	0	3	0	0	0	2	6	
REGION V													
IL	0	1	0	19	0	30	0	0	0	0	1	51	
IN	1	0	0	10	0	1	2	0	0	0	0	14	
MI	1	0	0	0	0	0	0	0	0	0	0	1	
MN	0	0	0	0	0	0	0	0	0	0	0	0	
OH	34	0	0	34	0	0	4	0	0	0	0	72	
WI	0	0	0	0	0	0	0	0	0	0	0	0	

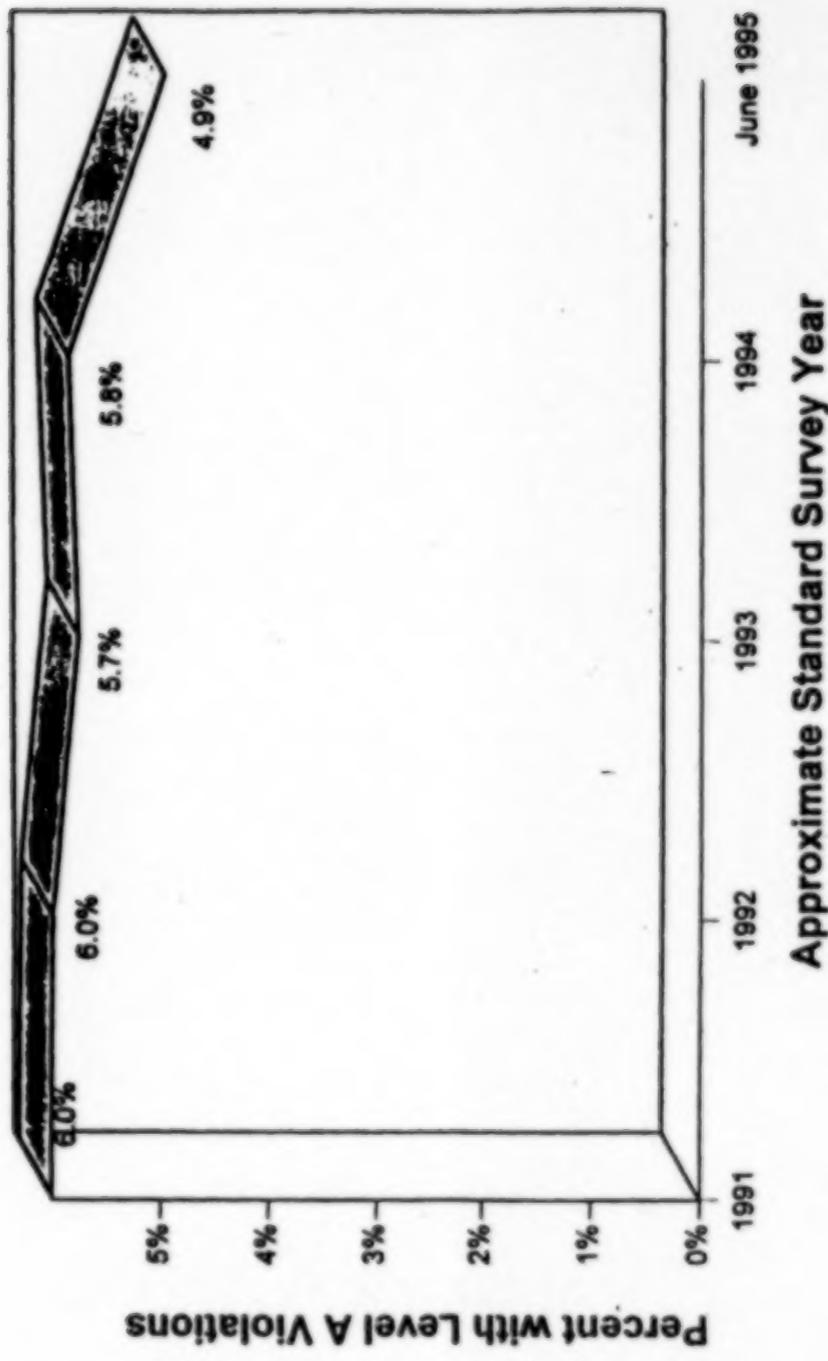
Sheet 1

REMEDIES	REMEDIES FORMALLY IMPOSED											TOTALS	KEY
	1	2	3	4	5	6	7	8	9	10	11		
REGION VI													
AR	0	0	0	5	0	0	0	0	0	0	0	5	1 State Monitoring
LA	0	0	0	2	0	0	0	0	0	0	0	2	2 Directed PoC
NM	1	1	0	0	0	0	0	0	0	0	0	2	3 Temporary Manager
OK	0	0	0	2	0	1	0	0	0	0	0	3	4 Denial of Pmt - New
TX	5	5	0	37	0	17	29	0	0	0	1	94	5 Denial of Pmt - All
REGION VII													6 Directed Inservice
IA	3	0	0	2	0	0	1	0	0	0	0	6	7 CMP
KS	23	0	0	18	0	0	13	0	0	0	0	54	8 Alt State Remedy
MO	1	1	0	0	0	0	2	0	0	0	1	5	9 Transfer/Closure
NE	1	0	0	0	0	0	0	0	0	0	0	1	10 Transfer
REGION VIII													11 Termination
CO	0	0	0	0	0	0	0	0	0	0	0	0	
MT	0	0	0	0	0	0	0	0	0	0	0	0	
ND	0	0	0	0	0	0	0	0	0	0	0	0	
SD	0	0	0	0	0	0	0	0	0	0	0	0	-
UT	0	0	0	0	0	0	0	0	0	0	0	0	
WY	0	1	0	1	0	1	0	0	0	0	0	3	
REGION IX													
AZ	0	0	0	0	0	0	0	0	0	0	0	0	
CA	29	5	4	19	0	3	0	0	0	2	0	62	
HI	0	0	0	0	0	0	0	0	0	0	0	0	
NV	0	6	2	3	0	0	0	0	0	0	0	11	
REGION X													
AK	0	0	0	1	0	0	0	0	0	0	0	1	
ID	0	0	0	0	0	0	1	0	0	0	0	1	
OR	0	0	0	13	0	1	2	0	0	0	0	16	
WA	0	3	0	11	0	0	0	0	0	0	0	14	
TOTALS	106	125	10	192	6	67	94	5	1	2	21	629	

[Exhibit D to Amended Complaint]

Figure 15

Trends in Percent of Facilities with Level A Violations



[Exhibit E to Amended Complaint]

1994 ILLINOIS DEPARTMENT OF PUBLIC HEALTH LONG-TERM CARE FACILITY STATEWIDE SUMMARY PROFILE

HEALTH SERVICE AREA LTC PLANNING AREA Illinois	2. ADMISSION RESTRICTIONS	AVERAGE DAILY PAYMENT RATES										5. STAFFING PATTERNS				
		LEVEL OF CARE		SINGLE	DOUBLE	EMPLOYMENT CATEGORY		FULL-TIME	PART-TIME							
	Aggressive Behavior	578				Administrators		1404	149							
	Chronic Alcoholism	692				Physicians		376	312							
	Developmentally Disabled	533				Director of Nursing		1046	33							
	Drug Addiction	805				Registered Nurses		6121	3407							
TOTAL FACILITIES	1220	Nursing Recipient	130			LPNs		7226	2775							
HOSPITAL-BASED UNITS	92	Medicard Recipient	192			Certified Aides		30765	8457							
FREE-STANDING FACILITIES	1128	Mental Illness	683			Other Health Staff		4442	1290							
FACILITIES LICENSED FOR:		Non-Ambulatory	156			Other Non-Health Staff		25280	8547							
NURSING CARE BEDS ONLY	776	Non-Mobile	202			TOTAL STAFF		76880	24970							
SHELTERED CARE BEDS ONLY	51	Public Aid Recipient	123													
DO CARE BEDS ONLY	301	Under 65 Years Old	67													
FACILITIES BY OWNERSHIP TYPE		Not Self-Medicating	164													
GOVERNMENTAL	74	DEVELOPMENTALLY DISABLED		6. LONG-TERM CARE BEDS BY LEVEL OF CARE												
NON-PROFIT	522	RESIDENTS PERMITTED		LEVEL OF CARE	LICENSED BEDS		BEDS IN USE		MEDICARE CERTIFIED		MEDICAID CERTIFIED					
FOR PROFIT	624	UNDER BOGARD		Skilled	65960		39017		13779		10584					
				Intermediate	36976		51728				81158					
				Sheltered Care	7531		5570									
				Skilled under 22	1157		945									
				Intermediate 60	7181		6842									
				TOTAL BEDS	118805		104902		13779		100100					
7. RESIDENTS BY AGE GROUP, SEX AND LEVEL OF CARE - DECEMBER 31, 1994		8. RESIDENTS BY AGE GROUP, SEX AND PAYMENT SOURCE - DECEMBER 31, 1994														
AGE GROUPS	SKILLED	INTERMEDIATE	SHELTERED	UNDER AGE 22	INTERMED. 60		MEDICARE	MEDICAID	OTHER PUBLIC	INSURANCE	PRIVATE PAY					
IN YEARS	Male	Female	Male	Female	Male	Female	Male	Female	Male	Female	Male					
Under 18	5	7	0	1	0	278	219	1	1	2	0	13	3	204		
18 to 44	390	238	1858	1020	224	224	211	2116	1990	25	20	4386	3244	3423		
45 to 59	381	362	2138	1923	258	114	2	1000	848	56	50	3197	2809	8235		
60 to 64	262	291	1318	1518	90	72	0	195	161	50	44	1510	1700	7007		
65 to 74	1132	1601	3806	6042	170	201	0	254	181	436	505	3761	5725	3248		
75 to 84	1925	4300	5965	16037	345	1249	0	68	76	767	1517	6556	11954	13545		
85 & Over	1495	3553	5255	24915	407	2203	0	0	0	467	1287	3255	16308	21662		
TOTALS	5610	12352	20418	51456	1554	3983	504	431	3634	3165	1796	3484	20932	32600		
9. RESIDENTS BY PAYMENT SOURCE AND LEVEL OF CARE		10. RESIDENTS BY RACIAL/ETHNIC GROUP										11. DD AND HI RESIDENTS BY SEX AND AGE GROUP				
LEVEL OF CARE	OTHER	MEDICARE	MEDICAID	PUBLIC	INSURANCE	PAT	TOTALS	RACIAL/ETHNIC	DD	HI	ALL OTHER	AGE GROUPS	DD Male	DD Female	HI Male	HI Female
Skilled	5283	6308	252	659	5396	17976		White	7691	7441	74027	Under 18	276	220	0	0
Intermediate		49078	853	264	21668	71063		Black	1231	2317	7962	18 to 44	2517	2227	1520	757
Sheltered			921	6	4610	5337		Asian	58	129	626	45 to 59	1206	1049	1312	1115
Under Age 22		907	2	1	25	935		Hispanic	216	210	831	60 to 64	258	249	533	563
Intermed. 60		6683	18	0	78	6799		Other	30	52	487	65 to 74	392	359	801	1252
TOTALS	5283	63056	2046	930	31795	103110		TOTAL	9226	10149	83733	75 & Over	169	223	430	1119
12. ADMISSIONS AND DISCHARGES - 1994		13. RESIDENTS BY PRIMARY DIAGNOSIS										14. ALZHEIMER'S DISEASE PATIENTS - DECEMBER 31, 1994				
A. Residents on January 1, 1994								Neoplasms	2401			AT. BY AGE GROUP				
B. Total Admissions 1994								Endocrine/Metabolic	6153			A2. BY RACIAL/ETHNIC GROUP				
C. Total Discharges 1994								Blood Disorders	1309			AGE GROUPS	MALE	FEMALE	RACIAL/ETHNIC	RESIDENTS
D. Residents on December 31, 1994								Mental Illness	10803			Under 18	0	0	White	11240
								Developmental Disability	9062			18 to 44	10	5	Black	1090
								Nervous System	8275			45 to 59	34	57	Asian	29
								Circulatory System	26311			60 to 64	104	151	Hispanic	84
								Respiratory System	4927			65 to 74	532	1039	Other	80
								Digestive System	2886			75 to 84	1267	3846	TOTALS	12523
								Genito-Urinary System	1977			85 & Over	947	4438		
								Skin Disorders	893			TOTALS	2894	9536		
								Muscle-Skeletal	6976							
								Injuries/Poisonings	3163							
								Other Medical	6462							
								Non-Medical Placement	877							
								TOTALS	90453							
												DEDICATED ALZHEIMER'S UNITS				113
												DEDICATED ALZHEIMER'S BEDS				5052
												DEDICATED ALZHEIMER'S MEDICARE BEDS				171

Source: Illinois Center for Health Statistics, Illinois Department of Public Health, 525 West Jefferson, Springfield, IL 62761 Telephone (217) 785-1064 September 1995

Supreme Court, U.S.
FILED

(6)
JUL 2 1999

No. 98-1109

RECEIVED
RECORD OF THE BRIEF

In the Supreme Court of the United States

DONNA E. SHALALA, SECRETARY OF HEALTH AND
HUMAN SERVICES, ET AL., PETITIONERS

v.

ILLINOIS COUNCIL ON LONG TERM CARE, INC.

ON WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE SEVENTH CIRCUIT

BRIEF FOR THE PETITIONERS

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13288

QUESTION PRESENTED

Whether 42 U.S.C. 405(h), incorporated into the Medicare Act by 42 U.S.C. 1395ii, permits skilled nursing facilities participating in the Medicare program to bring anticipatory, pre-enforcement lawsuits under 28 U.S.C. 1331 and 1346 (1994 & Supp. III 1997) to challenge the validity of Medicare program enforcement regulations and guidelines notwithstanding the Medicare Act's provision of an express, post-enforcement mechanism for administrative and judicial review.

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In the Supreme Court of the United States

No. 98-1109

DONNA E. SHALALA, SECRETARY OF HEALTH AND
HUMAN SERVICES, ET AL., PETITIONERS

v.

ILLINOIS COUNCIL ON LONG TERM CARE, INC.

*ON WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE SEVENTH CIRCUIT*

BRIEF FOR THE PETITIONERS

OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 1a-12a) is reported at 143 F.3d 1072. The memorandum and order of the district court (Pet. App. 13a-21a) is unreported.

JURISDICTION

The judgment of the court of appeals was entered on May 8, 1998. A petition for rehearing was denied on August 13, 1998 (Pet. App. 22a-23a). On November 2 and December 4, 1998, Justice Stevens extended the time within which to file a petition for a writ of certiorari, first to December 12, 1998, and then to January 10, 1999, a Sunday. The petition was filed on Monday, January 11, 1999, and was granted on April 19, 1999. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

STATUTORY AND REGULATORY PROVISIONS INVOLVED

Pertinent statutory and regulatory provisions are set forth in the appendix to this brief.

STATEMENT

The Health Insurance for the Aged Act, commonly known as the Medicare Act, Pub. L. No. 89-97, 79 Stat. 290, codified as amended, 42 U.S.C. 1395 *et seq.*, provides insurance for covered in-patient hospital and post-hospital services, 42 U.S.C. 1395x(m), including skilled nursing care. 42 U.S.C. 1395f(b)(1), 1395i-3, 1395x(v)(1)(A).¹ To receive payment for services provided to Medicare beneficiaries, a skilled nursing facility must enter into a provider agreement with the Secretary of Health and Human Services (HHS), and meet "requirements of participation" relating to beneficiary health, safety, and care. See 42 U.S.C. 1395i-3(a) to (d). Respondent, a trade association that represents nursing facilities participating in the Medicare program in Illinois, brought this suit to challenge the methods by which the Secretary assesses compliance with Medicare's health, safety, and quality-of-care requirements and selects remedies when non-compliance is detected. The question before the Court is whether a federal district court may entertain such a pre-enforcement challenge under the general grant of federal-question jurisdiction contained in 28 U.S.C. 1331, notwithstanding the Medicare Act's provision of express post-enforcement mechanisms for judicial review.

¹ Such coverage is provided through Part A of the program. Part B of Medicare is a voluntary supplementary insurance program covering physicians' charges and other medical services. 42 U.S.C. 1395k, 1395l, 1395x(s). The recently enacted Part C of Medicare authorizes beneficiaries to obtain covered Medicare services through Health Maintenance Organizations and other "managed care" arrangements. Balanced Budget Act of 1997, Pub. L. No. 105-33, Tit. IV, § 4001, 111 Stat. 276-327. Only Part A of the program is at issue here.

1. The Social Security Act was passed in 1935 to provide retirement and related benefits for the elderly. See ch. 531, 49 Stat. 620. Four years later, Congress amended the Act by adding express provisions for administrative and judicial review. See Social Security Act Amendments of 1939, ch. 666, 53 Stat. 1360; see S. Rep. No. 734, 76th Cong., 1st Sess. 51 (1939); H.R. Rep. No. 728, 76th Cong., 1st Sess. 42 (1939). Those provisions now appear (as amended) at 42 U.S.C. 405(b), (g) and (h).

Section 405(b) provides that any individual who is dissatisfied with an agency determination is entitled to "notice and opportunity for a hearing with respect to" the determination. 42 U.S.C. 405(b). Section 405(g), in turn, provides that anyone dissatisfied with a "final decision * * * made after a hearing to which he was a party may * * * obtain a review of such decision by" filing an action in district court. 42 U.S.C. 405(g). Finally, 42 U.S.C. 405(h) renders the administrative and judicial review procedures under Section 405(b) and (g) exclusive. It declares:

The findings and decisions of the Commissioner of Social Security after a hearing shall be binding upon all individuals who were parties to such hearing. No findings of fact or decision of the Commissioner of Social Security shall be reviewed by any person, tribunal, or governmental agency except as herein provided. No action against the United States, the Commissioner of Social Security, or any officer or employee thereof shall be brought under sections 1331 or 1346 of title 28 to recover on any claim arising under this subchapter.

42 U.S.C. 405(h). (Section 1331 of Title 28 accords federal courts general federal-question jurisdiction, and 28 U.S.C. 1346 provides jurisdiction over cases in which the United States is a defendant.)

In 1965, Congress amended the Social Security Act by adding Title XVIII—the Medicare Act—to furnish medical

insurance for the elderly and disabled. Pub. L. No. 89-97, § 102, 79 Stat. 291, codified as amended at 42 U.S.C. 1395 *et seq.*; see p. 1, *supra*. Rather than enact separate provisions for review of Medicare claims, Congress incorporated the hearing and judicial review mechanisms of 42 U.S.C. 405(b), (g), and (h) into the Medicare program.² For example, 42 U.S.C. 1395ff(a) and (b) provide that any “individual dissatisfied with” the determination by the Secretary of Health and Human Services respecting either his “entitle[ment]” to or the “amount” of benefits under Medicare is entitled to “a hearing thereon * * * to the same extent as is provided in Section 405(b) * * * and to judicial review of the Secretary’s final decision after such hearing as is provided in Section 405(g).” 42 U.S.C. 1395ff(a) and (b).

The Medicare Act makes those same hearing and judicial review provisions applicable to decisions affecting institutions, such as skilled nursing facilities, that provide services to Medicare beneficiaries. For example, nursing facilities may receive reimbursement under Medicare only if they have a provider agreement with the Secretary and they meet statutory requirements relating to patient health, safety, and care; they must be certified as meeting statutory requirements on average once a year. 42 U.S.C. 1395i-3(b) to (d), 1395cc. If a provider wishes to dispute a determination

² Although 42 U.S.C. 405(b), (g), and (h) refer to the “Commissioner of Social Security,” Congress declared that, in applying those provisions to the Secretary’s decisions under Medicare, any reference to the Commissioner of Social Security shall be construed as a reference to the Secretary. See 42 U.S.C. 1395cc(h), 1395ii. As originally enacted, Section 405(b), (g), and (h) referred directly to the Secretary, but Congress changed those provisions so they would refer instead to the Commissioner of Social Security in 1994, when Congress established the Social Security Administration as a separate agency and made it responsible for administration of the social security program. See Social Security Independence and Program Improvements Act of 1994, Pub. L. No. 103-296, § 106(d), 108 Stat. 1476.

concerning compliance or certification—or termination or non-renewal of its provider agreement—42 U.S.C. 1395cc(h) provides that it may do so through the hearing and review procedures under 42 U.S.C. 405(b) and (g).³ It thus states:

[A]n institution or agency dissatisfied with a determination by the Secretary that it is not a provider of services or a determination described in subsection (b)(2) of this section shall be entitled to a hearing thereon by the Secretary (after reasonable notice) to the same extent as is provided in section 405(b) [of Title 42], and to judicial review of the Secretary’s final decision after such hearing as is provided in section 405(g) [of Title 42].

42 U.S.C. 1395cc(h). The determinations “described in subsection (b)(2)” include, among other things, a determination “that the provider fails to comply substantially with the provisions of [its provider agreement or] with the provisions of [the Medicare Act] and regulations thereunder.”⁴ Different provisions of the Medicare Act added after 1965 similarly channel other decisions affecting Medicare providers, including decisions determining provider reimbursement or imposing civil money penalties for violations, through spe-

³ Originally, 42 U.S.C. 1395cc(h) appeared as subsection (c) of 42 U.S.C. 1395ff. See 42 U.S.C. 1395ff(c) (1976). When the Act was amended in 1987 (see pp. 7-8, *infra*), the provision was moved to its current location in 42 U.S.C. 1395cc(h).

⁴ A finding that a facility fails to meet statutory or regulatory standards for health or safety, and that imposes certain remedies as a result, might also be considered a determination that the facility “is not a provider of services.” See 42 U.S.C. 1395i-3(a)(3) (defining provider of services as a facility that meets statutory and regulatory requirements); *Michigan Ass’n of Homes & Servs. for the Aging, Inc. v. Shalala*, 127 F.3d 496, 501 & n.3 (6th Cir. 1997).

cific statutory mechanisms for administrative and judicial review.⁵

Finally, the Medicare Act makes 42 U.S.C. 405(h)—the provision of Title II of the Social Security Act that declares the Secretary's decisions to be binding, prohibits review of any decision except as provided in the Act itself, and deprives federal courts of jurisdiction under 28 U.S.C. 1331 and 1346—applicable to the Medicare program. Specifically, Section 1395ii declares that “[t]he provisions of * * * subsections (a), (d), (e), (h), (i), (j), (k), and (l) of section 405 of this title, shall also apply with respect to this subchapter to the same extent as they are applicable with respect to [Title II].”

2. Notwithstanding the Medicare program's health and safety requirements for provider participation, a 1986 survey by the Institute of Medicine of the National Academy of Sciences found that, in many “government certified nursing homes, individuals * * * receive very inadequate—sometimes shockingly deficient—care that is likely to hasten the deterioration of their physical, mental, and emotional health.” H.R. Rep. No. 391, 100th Cong., 1st Sess., Pt. 1, at 452 (1987). A Government Accounting Office survey also

⁵ Under Part A, initial reimbursement determinations affecting participating providers are made by fiscal intermediaries operating under contract with the Health Care Financing Administration (HCFA). 42 U.S.C. 1395h. Pursuant to 42 U.S.C. 1395o(a), which was enacted in 1972, Pub. L. No. 92-603, § 243(a), 86 Stat. 1420, a provider that “is dissatisfied with a final determination” and timely files objections meeting amount-in-controversy requirements may obtain a hearing before the Provider Reimbursement Review Board (PRRB). The decisions of the PRRB are final (although the Secretary has the right to affirm, reverse, or modify them within 60 days); and, pursuant to 42 U.S.C. 1395o(f), judicial review is available in district court. See *Your Home Visiting Nurse Servs., Inc. v. Shalala*, 119 S. Ct. 930, 932-933 (1999). Where the Secretary imposes civil money penalties under 42 U.S.C. 1320a-7a, a hearing is available under 42 U.S.C. 1320a-7a(c)(2), and review in the court of appeals is available under 42 U.S.C. 1320a-7a(e). See Medicare and Medicaid Amendments of 1981, Pub. L. No. 97-35, Tit. XXI, § 2105, 95 Stat. 789.

reported widespread deficiencies, *ibid.*, and testimony before Congress confirmed (sometimes in grim detail) extensive problems, such as unsanitary conditions, pervasive neglect, and instances of serious abuse. See generally *1 Nursing Home Care—The Unfinished Agenda: Hearing Before the Senate Special Comm. on Aging*, 99th Cong., 2d Sess. (1986) (1986 Hearing).⁶ As one observer summarized, Medicare's compliance regime had “failed, * * * somewhat dismally, to assure a decent level of patient care” to nursing facility residents. *Id.* at 2. That failure, Congress concluded, was in part the product of a system that focused on the facility's theoretical capacity to provide care, *i.e.*, paper qualifications and physical characteristics, rather than on the actual care provided to beneficiaries. H.R. Rep. No. 391, *supra*, Pt. 1, at 466-467. And it resulted in part from the limited effectiveness of the only enforcement remedy available to the Secretary—termination of the provider agreement permitting the facility to participate in the Medicare program. That regime led to a “yo-yo” effect, under which facilities with serious health, safety, and quality-of-care deficiencies would remedy them just in time to avoid termination, but fall into noncompliance once again immediately thereafter. *Id.* at 471.⁷

⁶ For example, surveyors and others found nursing home residents lying in their own feces or urine for extended periods of time, covered with flies and dried food, and ridden with bedsores, despite complaints from visiting relatives. 1986 Hearing 8-9, 61, 64, 800. There were reports of patients dying when facilities failed to pay attention to their medical needs. See, e.g., *id.* at 110 (patient died of starvation after facility failed to ensure feeding tube provided sufficient calories); *id.* at 73-74 (patient died from absence of medical attention for severe cramps and vomiting). And there were disturbingly frequent reports of brain-impaired and comatose patients being raped and sexually abused. *Id.* at 105-106.

⁷ As the House Report explained, nursing homes knew “in advance that they [would] not be penalized” by termination even “if caught with serious deficiencies as long as they correct[ed] them sufficiently” after inspection. As a result, the deterrent value of that remedy was relatively slight. H.R. Rep. No. 391, *supra*, Pt. 1, at 471.

Congress responded in 1987 by comprehensively reforming the requirements of participation for skilled nursing facilities, altering the manner in which compliance is enforced, and expanding the range of available remedies. See Omnibus Budget Reconciliation Act of 1987 (OBRA), Pub. L. No. 100-203, §§ 4201-4218, 101 Stat. 1330-160 to 1330-221. Among other things, OBRA requires that skilled nursing facilities be subjected to inspection without prior notice on average once a year. 42 U.S.C. 1395i-3(g)(2)(A)(i) and (iii). Although surveys are generally under the control of state agencies, 42 U.S.C. 1395i-3(g)(1)(A),⁸ federal law governs the qualifications of survey team members, prescribes survey methods and procedures, and requires the use of federal forms. 42 U.S.C. 1395i-3(g)(2)(C); see also 42 C.F.R. 488.26(c), 488.314. Survey information must be made available to the public, 42 U.S.C. 1395i-3(g)(5)(A), and information about some types of substandard care must be provided to certain state officials, licensing boards, and physicians, 42 U.S.C. 1395i-3(g)(5)(B) to (C); see also 42 C.F.R. 488.325. The statute also directs the Secretary to develop enforcement criteria and to minimize the time between the detection of deficiencies and the imposition of a remedy. 42 U.S.C. 1395i-3(h)(2)(B).

When a survey agency detects a deficiency, it must recommend a remedy to the Secretary, who can approve the remedy or select a different one. 42 U.S.C. 1395i-3(h)(1). If the facility substantially complies with health, safety, and quality of care requirements—that is, if “any identified deficiencies pose no greater risk to resident health or safety

⁸ State agencies conduct the surveys pursuant to contracts with the Secretary, see 42 U.S.C. 1395i-3(g)(1)(A), 1396aa, but the Secretary may survey public nursing facilities operated by state or local governments and may survey any other facility if she has reason to question the facility's compliance with the statute, 42 U.S.C. 1395i-3(g)(3)(D), or it is necessary to assess survey agency performance, 42 U.S.C. 1395i-3(g)(3)(A).

than the potential for causing minimal harm,” 42 C.F.R. 488.301—no remedy is imposed.⁹ Where substantial compliance is not found, however, the Secretary may impose a remedy from an expanded list of options; she may direct the creation of a plan for correcting violations, impose civil money penalties, deny further reimbursement for services rendered after the deficiency is discovered, appoint temporary management, or terminate a facility's right to participate in Medicare. 42 U.S.C. 1395i-3(h)(2); 42 C.F.R. 488.406. In general, the remedies selected depend on the seriousness of the violations. See 42 U.S.C. 1395i-3(h)(2)(B); see also 42 C.F.R. 488.408 (grouping violations into 3 categories). Thus, the Secretary's regulations require survey agencies to determine whether the violations have already resulted in actual harm to residents, the potential for harm the violations pose, the degree of that potential harm, and whether the violations place residents in “immediate jeopardy,” i.e., whether the violations have “caused, or [are] likely to cause, serious injury, harm, impairment, or death to a resident.” 42 C.F.R. 488.301, 488.404(b)(1). The survey agency also must consider whether the violations are isolated, form a pattern, or are widespread. 42 C.F.R. 488.404(b)(2). Other factors relevant to remedy selection include the relationship among deficiencies and the facility's compliance history. 42 C.F.R. 488.404(c). In general, the Secretary is expected to use available enforcement mechanisms to “bring substandard facilities into compliance with [federal] quality of care re-

⁹ The regulations governing nursing home surveys and remedies for violations apply to both the Medicaid program, which is administered jointly by the States and the Secretary, and the Medicare program, which is administered by the Secretary (although state agencies conduct Medicare nursing home surveys for the Secretary under contract). See 42 C.F.R. 488.300, 488.400. Some of the regulations therefore refer to enforcement actions taken by the State as well as by HCFA on behalf of the Secretary. See, e.g., 42 C.F.R. 488.402(b).

quirements or to exclude them from the program." H.R. Rep. No. 391, *supra*, Pt. 1, at 452.

Where relatively serious violations grouped under the heading "substandard quality of care" are found,¹⁰ the agency must evaluate the facility's operations in greater depth and identify the policies and procedures that caused the deficiency. 42 U.S.C. 1395i-3(g)(2)(B). Nursing facilities that are subjected to such an extended survey because of substandard care lose their eligibility to conduct a certified nurse-aide training program for two years, 42 U.S.C. 1395i-3(f)(2)(B)(iii), and three consecutive findings of substandard quality of care trigger automatic sanctions, such as a denial of payment for new admissions until the facility achieves, and can demonstrate that it is able to maintain, substantial compliance, 42 U.S.C. 1395i-3(h)(2)(E); 42 C.F.R. 488.414.

Nursing homes must be afforded written notice of deficiencies noted in any survey, of the remedy (if any) to be imposed, and of appeal rights. 42 C.F.R. 488.330, 488.414. A facility that disagrees with the survey may invoke a formal dispute-resolution process before the survey agency. That process must afford the nursing facility a prompt and meaningful opportunity to refute any findings of deficient care. 42 C.F.R. 488.331.¹¹ Whether or not the facility in-

vokes the informal dispute resolution process, any facility subjected to a remedy for noncompliance is entitled to a hearing before an administrative law judge (ALJ). See 42 U.S.C. 1395cc(h); 42 C.F.R. 498.1(a)-(b), 498.3(a), 498.3(b)(12). At that hearing, the facility may be represented by counsel, call witnesses, and present evidence. 42 C.F.R. 498.40-498.78. Any nursing facility dissatisfied with the resulting "decision may request Departmental Appeals Board review." 42 C.F.R. 498.5(c). Where civil money penalties are imposed, the decision of the Departmental Appeals Board is subject to judicial review through a petition to the court of appeals. 42 U.S.C. 1395i-3(h)(2)(B)(ii); 42 U.S.C. 1320a-7a(e); see also 42 U.S.C. 1395cc(h)(2). In all other cases, "judicial review of the Secretary's final decision" is available in district court as provided in 42 U.S.C. 405(g). 42 U.S.C. 1395cc(h)(1). See generally pp. 4-6 & n.5, *supra*.

3. Respondent filed this action in the United States District Court for the Northern District of Illinois in 1996 seeking injunctive and declaratory relief with respect to the implementing regulations the Secretary issued in 1995. The complaint does not challenge the Secretary's substantive standards governing resident health, safety, and care. J.A. 17, 22, 36-37 (¶¶ 1, 16, 64). Instead, respondent broadly challenges the procedures and remedies used in enforcing those standards.

More specifically, respondent alleges that the Secretary's regulations concerning the characterization of the seriousness of violations are unconstitutionally vague. J.A. 18, 29-32, 43-45 (¶¶ 3B, 37-50, 84-88). According to respondent,

¹⁰ "Substandard quality of care" exists where serious violations of the statutory requirements most directly related to medical care and the residents' quality of life either (1) create immediate jeopardy to resident health and safety, (2) constitute a pattern of or widespread actual harm that falls short of immediate jeopardy, or (3) pose a widespread potential for more than minimal harm even if no actual harm has yet occurred. 42 C.F.R. 488.301.

¹¹ Under the prior regulatory scheme, many States had successfully employed various types of informal appeal procedures to handle compliance disputes. 59 Fed. Reg. 56,116, 56,224 (1994). Because those procedures had proven effective and efficient, the Secretary directed all States to establish similar processes. *Id.* at 56,224-56,225. Although the regulations give the States discretion concerning the form and content of

such procedures, the process as a whole must afford nursing homes a meaningful opportunity to refute findings of deficient care. 42 C.F.R. 488.331(a)(1). If the provider successfully rebuts a survey finding, the State must remove the deficiency from its findings and rescind any proposed enforcement action based on that determination. 42 C.F.R. 488.331(c). Similar procedures are also available with respect to federally-conducted surveys. 42 C.F.R. 488.331(a)(2).

critical terms such as “minimal harm,” “immediate jeopardy,” “pattern,” and “widespread,” are not defined with sufficient particularity. See J.A. 30-31 (¶¶ 42-44). Respondent further claims that, because of that asserted vagueness, remedies are not imposed in a consistent fashion. J.A. 18, 36-38, 45, 46 (¶¶ 3C, 64-68, 89-91, 94).

Respondent also alleges that the Secretary’s regulations are inconsistent with due process because they limit the scope of administrative review. J.A. 18-19, 32-36, 47-49 (¶¶ 3D-3E, 51-63, 95-101). In particular, respondent complains that administrative review of survey findings is not available if no remedy is imposed, J.A. 34-35, 48-49 (¶¶ 59, 99, 101), or as to matters such as the surveyors’ characterization of the level of noncompliance (except where it affects the permissible range of civil penalties) and the remedy selected, J.A. 34, 48-49 (¶¶ 57-58, 101). See generally 42 C.F.R. 498.3(b)(12) and (13), (d)(10) and (11). Respondent also protests the absence of a prior hearing before certain remedies, such as termination of the provider agreement, are imposed. J.A. 18-19 (¶ 3D).¹² Finally, the complaint alleges that a manual used by state survey inspectors to review facilities for compliance—the State Operations Manual or SOM—is a substantive rule that was promulgated outside the notice-and-comment rulemaking process required by the Administrative Procedure Act (APA), 5 U.S.C. 553. J.A. 18, 26-28, 46 (¶¶ 3A, 30-36, 92-94).

Respondent seeks an order declaring that (1) the Secretary’s regulations are unconstitutionally vague, (2) the State Operations Manual was promulgated in violation of the APA,

¹² Respondent also complains that, under current regulations, no administrative review is available where a finding of “substandard quality of care” causes the facility (automatically) to lose approval for its nurse-aide training program but no other remedy is imposed. J.A. 33 (¶¶ 54-55); see 42 C.F.R. 498.3(b)(12) and (d)(10)(ii). We have been informed by the Department of Health and Human Services that it is currently reviewing that exclusion.

and (3) the administrative appeal procedures provided under the current regulations are inadequate. J.A. 51 (¶¶ A, C, D). Respondent also seeks an injunction precluding the Secretary from (1) disclosing survey results where “substandard quality of care” is found; (2) imposing or collecting civil money penalties; and (3) imposing “upon [respondent’s] Medicare members any ban on payment as a remedy for any deficiency.” J.A. 52 (¶¶ E, F, G). Subject matter jurisdiction is premised on 28 U.S.C. 1331, 1346, and 2201. J.A. 22 (¶ 14); Pet. App. 13a, 15a.

The district court dismissed the complaint for lack of subject matter jurisdiction. Pet. App. 13a-21a. The court pointed out that, under 42 U.S.C. 405(h), a federal district court may not assert jurisdiction under 28 U.S.C. 1331 or 1346 with respect to claims arising under the Medicare Act. In this case, the court reasoned, respondent’s claims clearly arise under the Medicare Act, and it therefore could not assert jurisdiction under 28 U.S.C. 1331 and 1346. Pet. App. 15a-18a.

The district court also rejected respondent’s reliance on *Bowen v. Michigan Academy of Family Physicians*, 476 U.S. 667 (1986). See Pet. App. 18a-19a. In *Michigan Academy*, this Court held that 28 U.S.C. 1331 gave a federal district court jurisdiction over a facial challenge to the validity of Medicare regulations governing the methodology for calculating payments under Part B of the Medicare program. At the time *Michigan Academy* was decided, the Medicare Act (through 42 U.S.C. 1395ff (1982)) provided for a hearing and judicial review, under 42 U.S.C. 405(b) and (g), of decisions regarding the amount of payment (if any) due for particular services under Part A of the Medicare program, but not under Part B, see 476 U.S. at 674 n.5, and the Court had already held in *United States v. Erika, Inc.*, 456 U.S. 201, 207-208 (1982), that Congress thereby had completely foreclosed judicial review of administrative decisions concerning the amount of benefits payable under Part B. In *Michigan*

Academy, however, the Court, relying on the “strong presumption that Congress intends judicial review of administrative action,” held that the Medicare Act does not preclude “challenges mounted against the *method* by which [the] amounts [of Part B benefits] are to be determined rather than [challenges to] the [amount] determinations themselves.” 476 U.S. at 670, 675.

In light of the statutory framework and this Court’s analysis, the district court in this case concluded that *Michigan Academy* was premised on the fact that the plaintiffs there had “no other avenue of judicial review” to challenge the Secretary’s regulations. Pet. App. 18a. Here, in contrast, the Medicare Act itself provides an avenue through which respondent’s members can challenge the relevant enforcement procedures any time they are applied to the members themselves. *Ibid.* Moreover, the district court continued, Congress amended the Medicare Act shortly after the Court’s decision in *Michigan Academy*, and the amendment now provides administrative and judicial review under 42 U.S.C. 405(b) and (g) for the sort of Part B methodology challenges that were at issue in that case. See Omnibus Budget Reconciliation Act of 1986, Pub. L. No. 99-509, § 9341(a)(1), 100 Stat. 2037 (codified at 42 U.S.C. 1395ff(1)). Because both Part A and Part B participants “now have an avenue of judicial review,” the district court explained, “the concern * * * in *Michigan Academy*”—that agency action would be altogether immune from judicial review—“no longer exists.” Pet. App. 18a.

The district court further found that respondent had not satisfied the prerequisites for judicial review under 42 U.S.C. 405(g) (as made applicable here by 42 U.S.C. 1395cc(h)(1)), including the non-waivable requirement that all claims be presented to the Secretary, and the waivable requirement that administrative remedies be exhausted. Pet. App. 18a-19a. Here, the court observed, respondent

“ha[d] not alleged or shown any attempt at presentment of [its] claims to the Secretary.” *Id.* at 19a.¹³

4. The court of appeals vacated and remanded. Pet. App. 1a-12a. It acknowledged that this Court’s decisions in *Heckler v. Ringer*, 466 U.S. 602 (1984), and *Weinberger v. Salfi*, 422 U.S. 749 (1975), “treat th[e] language [of 42 U.S.C. 405(h)] as channeling all claims to benefits through the administrative forum, no matter what legal theory underlies the claim.” Pet. App. 4a. Relying on *Michigan Academy*, however, the court of appeals concluded that Section 405(h) addresses only provider claims relating to a “request for reimbursement,” *ibid.*, and does not apply to an “anticipatory challenge to implementing regulations,” *id.* at 5a.

The court of appeals agreed that “the 1986 amendments [to Part B],” which now provide an avenue of judicial review of Part B amount determinations and regulations through Section 405(g), might well “remove the practical support” for a distinction between “pre-enforcement challenges to Medicare regulations * * * and requests for reimbursement.” Pet. App. 5a. It also recognized that “*Michigan Academy* [had] emphasized * * * the presumption that Congress has allowed some avenue of judicial review, and the Justices [had] read the statutes then in effect with that presumption in mind.” *Ibid.* But the court of appeals noted that Congress had not amended 42 U.S.C. 405(h) or 1395ii. The court therefore considered itself “obliged to follow” *Michigan Academy*, which it read as permitting pre-enforcement review of regulations notwithstanding 42 U.S.C. 405(h), even where (unlike in *Michigan Academy*) Congress has provided for judicial review under 42 U.S.C. 405(g). See Pet. App. 6a-7a.¹⁴

¹³ The district court also dismissed respondent’s claims brought under the *Medicaid* program. Pet. App. 19a-20a. The status of those claims is not at issue here. See note 14, *infra*.

¹⁴ The court of appeals affirmed on ripeness grounds dismissal of respondent’s vagueness challenge to the Secretary’s regulations, Pet. App.

The Secretary's petition for rehearing with suggestion of rehearing en banc was denied, although three judges voted to grant rehearing en banc. Pet. App. 22a-23a & n.2.

SUMMARY OF ARGUMENT

A. The Medicare Act establishes detailed mechanisms for obtaining judicial review of claims that arise under the Act. Of particular significance here, it provides for judicial review of a regulation after the regulation has been applied to the party seeking to challenge it, the party has presented its claim to the Secretary, and the Secretary has issued a final decision. Where the Act itself provides an express mechanism for obtaining judicial review, that mechanism is exclusive. That is clear not merely from the reticulated nature of the Act's review mechanisms, but also from the text of 42 U.S.C. 405(h), which, as incorporated into the Medicare program by 42 U.S.C. 1395ii, declares that "[n]o findings of fact or decision of the [Secretary] shall be reviewed by any person, tribunal, or governmental agency except as * * * provided" in the Medicare Act itself, and that "[n]o action against the United States, the [Secretary], or any officer or employee thereof shall be brought under sections 1331 or 1346 of title 28 to recover on any claim arising under this subchapter." As the Senate Report accompanying the Medicare Act explained, "[i]t is intended that the remedies provided by these review procedures shall be exclusive." S. Rep. No. 404, 89th Cong., 1st Sess., Pt. 1, at 55 (1965).

B. The court of appeals' decision permitting federal-question jurisdiction over "pre-enforcement" challenges to

10a-11a, and this Court denied respondent's conditional cross-petition for a writ of certiorari seeking review of that holding. See 119 S. Ct. 1459 (1999). The court of appeals also reinstated respondent's claims on behalf of its Medicaid-only members with respect to the Secretary's Medicaid regulations. Pet. App. 7a-8a. Our certiorari petition did not seek review of that aspect of the court of appeals' judgment. See Pet. i, 5.

the validity of Medicare regulations under 28 U.S.C. 1331, notwithstanding the availability of post-enforcement review, is at odds with the plain language of Section 405(h) and is inconsistent with *Heckler v. Ringer*, 466 U.S. 602 (1984); *Weinberger v. Salfi*, 422 U.S. 749 (1975), and *Mathews v. Eldridge*, 424 U.S. 319 (1976). Those precedents hold that where, as here, the plaintiff's standing and the substantive basis for the plaintiff's suit are based on the Social Security Act (including its Medicare title), review is available only as provided by the Act itself.

Nor is the court of appeals' decision supported by *Bowen v. Michigan Academy of Family Physicians*, 476 U.S. 667 (1986). Unlike this case, *Michigan Academy* involved Medicare claims for which there was no avenue of judicial review under the Medicare Act. As a result, precluding general federal-question jurisdiction over those claims would have left the plaintiffs with no means of securing judicial review of substantial questions concerning the administration of the Medicare program—a result that the Court found to be inconsistent with the strong presumption that Congress intends final agency action to be subject to judicial review. Thus, contrary to the decision below, *Michigan Academy* does not authorize federal-question jurisdiction over pre-enforcement challenges to Medicare regulations where, as here, the Medicare Act itself affords fully adequate means of judicial review.

C. Although respondent attempts to justify bypass of the Medicare Act's otherwise exclusive mechanisms by claiming that its statutory and constitutional claims cannot be raised in administrative proceedings, those claims can be raised on judicial review of the Secretary's final decision. This Court, moreover, has repeatedly rejected the suggestion that a party can bypass the otherwise exclusive mechanisms for review provided by the Social Security Act simply because it raises constitutional or other issues that would not ordinarily be addressed in the administrative process. "[T]he plain

words of the third sentence of 405(h) do not preclude constitutional challenges. They simply require that [the challenges] be brought under jurisdictional grants contained in the Act, and thus in conformity with the same standards which are applicable to nonconstitutional claims arising under the Act." *Salfi*, 422 U.S. at 762.

ARGUMENT

RESPONDENT'S PRE-ENFORCEMENT JUDICIAL CHALLENGE TO THE SECRETARY'S ENFORCEMENT GUIDELINES AND REMEDIES IS BARRED BY THE MEDICARE ACT

By incorporating 42 U.S.C. 405(g) and (h) into the Medicare Act through 42 U.S.C. 1395cc(h) and 1395ii, Congress established a specific and exclusive mechanism for obtaining judicial review of claims "arising under" the Medicare Act. Those provisions require a nursing facility or other participant in the Medicare program to challenge the Secretary's regulations and policies after they have been applied to that participant, thereby ensuring that challenges are of manageable proportions and are framed by a concrete, factual setting. And they route all challenges through the administrative process as a pre-condition to judicial review, thereby permitting the development of a factual record, allowing for refinement of legal issues, enabling the agency to apply its expertise to the specific issues raised, and affording the Secretary the opportunity to resolve the dispute on other grounds.

In this case, respondent seeks to bypass Medicare's established mechanisms for obtaining review by bringing an anticipatory challenge under 28 U.S.C. 1331 to the Secretary's regulations in the abstract, without reference to any specific enforcement action. That effort, however, cannot be reconciled with the Medicare "statute's language, structure, * * * purpose, [and] legislative history," especially given that the Act itself provides an opportunity for "meaningful

review." *Thunder Basin Coal Co. v. Reich*, 510 U.S. 200, 207 (1994). Indeed, the text of Section 405(h) prohibits such an effort in unmistakeable terms.

A. WHERE THE MEDICARE ACT PROVIDES A MECHANISM FOR OBTAINING JUDICIAL REVIEW, THAT MECHANISM IS EXCLUSIVE

1. a. The Medicare Act provides a highly "reticulated statutory scheme, which carefully details the forum and limits of review" of the Secretary's determinations. *Bowen v. Michigan Academy of Family Physicians*, 476 U.S. 667, 675 (1986). With respect to each of a number of categories of claims, the Act channels the claims through administrative and then judicial review *after* the Secretary has taken action (reimbursement, enforcement, etc.) directed at the person seeking review. Thus, individuals who are dissatisfied with entitlement and payment determinations, 42 U.S.C. 1395ff(a) and (b), providers aggrieved by reimbursement decisions, 42 U.S.C. 1395oo(a) and (f), and entities subjected to civil money penalties, 42 U.S.C. 1320a-7a(c)(2) and (e), all are afforded the opportunity for a hearing after the Secretary's initial determination, and for judicial review once the Secretary reaches a final decision. See also pp. 3-6, *supra*.

That same general scheme applies to nursing facilities seeking to challenge the Secretary's guidelines and remedies for enforcing the Medicare program's requirements for participation. In particular, any nursing facility or other provider "dissatisfied with a determination by the Secretary that it is not a provider of services" or a determination that it does not "substantially comply" with the Secretary's health, safety, and quality-of-care requirements "is entitled to a hearing thereon by the Secretary (after reasonable notice) to the same extent as provided in section 405(b) * * * and to judicial review of the Secretary's final decision after such hearing as is provided in section 405(g) [of Title 42]." 42 U.S.C. 1395cc(h)(1) and (b)(2); see pp. 4-5, *supra*.

Likewise, under 42 U.S.C. 1395i-3(h)(2)(B)(ii), a facility against which civil penalties have been assessed is entitled to a hearing, and judicial review in the court of appeals, as provided by 42 U.S.C. 1320a-7a(c)(2) and (e).

The provision of such a “detailed structure” for post-enforcement administrative and judicial review is, by itself, strong evidence that Congress intended to make that structure exclusive. See *Thunder Basin*, 510 U.S. at 207; *United States v. Erika, Inc.*, 456 U.S. 201, 208 (1982) (concluding that evidence of exclusivity is particularly strong “[i]n the context of” the Medicare Act’s “precisely drawn provisions”). See also *Board of Governors of the Fed. Reserve Sys. v. MCorp Fin., Inc.*, 502 U.S. 32, 43-44 (1991); *United States v. Fausto*, 484 U.S. 439, 448-449 (1988); *Whitney Nat'l Bank v. Bank of New Orleans & Trust Co.*, 379 U.S. 411, 420 (1965). By contrast, when Congress intends to permit pre-enforcement review notwithstanding specific post-enforcement review mechanisms, it typically enacts express statutory provisions so providing. See, e.g., *Harrison v. PPG Indus.*, 446 U.S. 578, 592-593 (1980). It has not done so here.¹⁵

b. Congress, in any event, has expressly provided that the post-enforcement mechanisms for judicial review in the Medicare Act are exclusive. When Congress provided for judicial review of Social Security decisions by enacting 42 U.S.C. 405(g), it paired that provision with 42 U.S.C. 405(h) to preclude judicial review by other means. And when Congress made 42 U.S.C. 405(g) applicable to compliance determinations under the Medicare program in 1965, it also made Section 405(h) applicable by enacting 42 U.S.C.

¹⁵ *Abbott Laboratories v. Gardner*, 387 U.S. 136 (1967), is not to the contrary. There, the Court permitted pre-enforcement review of an agency regulation absent express statutory authority, but only after determining that a statutory savings clause and the legislative history reflected Congress’s intent to preserve an established practice of exercising equitable jurisdiction over pre-enforcement challenges to similar agency actions. *Id.* at 142-144. See also *Thunder Basin*, 510 U.S. at 212.

1395ii. As incorporated into the Medicare Act, Section 405(h) provides:

The findings and decisions of the [Secretary] after a hearing shall be binding on all individuals who were parties to such hearing. No findings of fact or decision of the [Secretary] shall be reviewed by any person, tribunal, or governmental agency except as herein provided. No action against the United States, the [Secretary], or any officer or employee thereof shall be brought under sections 1331 or 1346 of title 28 to recover on any claim arising under this subchapter.

As this Court has observed, “the first two sentences of § 405(h) * * * assure that administrative exhaustion will be required,” *Weinberger v. Salfi*, 422 U.S. 749, 757 (1975), while the third sentence “provides that § 405(g), to the exclusion of 28 U.S.C. § 1331, is the sole avenue for judicial review for all ‘claim[s] arising under’ the Medicare Act.” *Heckler v. Ringer*, 466 U.S. 602, 614-615 (1984) (emphasis added). Section 405(h) thus “require[s] the exhaustion of available administrative procedures, * * * foreclose[s] jurisdiction under the general grant of federal-question jurisdiction, 28 U.S.C. § 1331, and * * * route[s] review through § [405(g)].” *Califano v. Sanders*, 430 U.S. 99, 103 n.3 (1977); see also *id.* at 110 (Stewart, J., concurring) (“I can see no reason in this case why the second sentence of § [405(h)] should not be read to mean exactly what it says—that the decision before us is reviewable under § [405(g)] or not at all.”).¹⁶

c. To the extent the text and structure of the Medicare Act could leave any doubt, the legislative history erases it. The 1965 Senate Report that accompanied the Medicare Act,

¹⁶ As noted above, where civil money penalties are imposed as a sanction for noncompliance, a hearing and judicial review are available to the extent provided for by 42 U.S.C. 1320a-7a. See 42 U.S.C. 1395i-3 (h)(2)(B)(ii). Where 42 U.S.C. 1320a-7a applies, 42 U.S.C. 405(h) applies too. See 42 U.S.C. 1320a-7(f)(3).

immediately after discussing the various methods for obtaining administrative and judicial review under the Act, declares: "It is intended that the remedies provided by these review procedures shall be exclusive." S. Rep. No. 404, 89th Cong., 1st Sess., Pt. 1, at 54-55 (1965) (emphasis added). A clearer expression of Congress's intent is difficult to imagine.

d. Finally, requiring nursing facilities like respondent's members to seek judicial review under Section 405(g) after first seeking relief in the administrative process is fair and sensible. It does not deny nursing facilities the opportunity for judicial review; it merely postpones review until such time as the claim has arisen in a specific, factual context, the matter has been presented to the Secretary, and the Secretary has issued a final decision. See *Salfi*, 422 U.S. at 762. Moreover, channeling Medicare claims through the statutorily-provided mechanisms for administrative and judicial review serves important policy goals. First, by requiring that challenges be brought in the context of a specific enforcement action, the Act ensures that "the scope of the controversy [will be] reduced to more manageable proportions, and its factual components fleshed out, by some concrete action applying the regulation to the claimant's situation in a fashion that harms or threatens to harm him." *Lujan v. National Wildlife Fed'n*, 497 U.S. 871, 891 (1990); see *Reno v. Catholic Soc. Servs., Inc.*, 509 U.S. 43, 58-59 (1993) (noting, for similar reasons, that mere passage of a statute and issuance of regulations do not give a complainant a ripe claim absent agency action "applying the regulation to him"). Second, the process required by Section 405(g) and (h) promotes the interest in administrative efficiency by protecting the agency from the "potential for overly casual * * * judicial intervention in an administrative process" that is responsible not only for protecting the health and safety of thousands of Medicare beneficiaries residing in nursing homes, but also for resolving "millions of claims" a year. *Ringer*, 466 U.S. at 627; see also *Salfi*, 422 U.S. at 765.

Third, channeling claims through the administrative process promotes judicial economy. It permits the agency "to correct its own errors, to afford the parties and the courts the benefit of its experience and expertise, and to compile a record which is adequate for judicial review." *Salfi*, 422 U.S. at 765; accord *Ringer*, 466 U.S. at 619 n.12. Further, it may avert the need for judicial review altogether, as it "assures the Secretary the opportunity prior to * * * litigation to ascertain, for example, that the particular claims involved are neither invalid for other reasons nor allowable under other provisions of the Social Security Act." *Salfi*, 422 U.S. at 762.

2. Consistent with the text, structure, history, and purposes of the Social Security Act's review provisions, the Court repeatedly has recognized that, where those provisions create a mechanism for judicial review, that mechanism is exclusive. In *Salfi*, for example, the Court held that a federal district court lacked jurisdiction under 28 U.S.C. 1331 to hear a constitutional challenge to a provision of the Social Security Act that rendered the plaintiffs ineligible for certain benefits. The language of Section 405(h), the Court held, is "sweeping and direct"; it states "that no action shall be brought under § 1331" with respect to any claim "arising under" the Social Security Act. 422 U.S. at 757. The Court in *Salfi* also rejected the argument that Section 405(h) does not apply if the suit can be characterized as "arising under" the Constitution. Where "the Social Security Act * * * provides both the standing and the substantive basis for the presentation of their constitutional contentions," the Court held, the plaintiffs' action is a suit "arising under" the Act within the meaning of Section 405(h), even if the suit could be said to arise under the Constitution as well. 422 U.S. at 760-761. Consequently, where such claims are asserted, Section 405(h) precludes federal courts from exercising jurisdiction over them pursuant to 28 U.S.C. 1331; instead, judicial review is available only through the mechanisms

provided by the Social Security Act itself. 422 U.S. at 760-761.

Seven years later, the Court again stressed the exclusivity of the Act's review mechanisms in *United States v. Erika, Inc.*, 456 U.S. 201 (1982). There, a company that had provided services to Medicare beneficiaries sought to challenge the amount of reimbursement it received under Part B of the Medicare program. At that time, the Act provided for judicial review of decisions under both Part A and Part B where the "dispute relates to * * * eligibility to participate," but provided for judicial review of determinations concerning the "amount" of payment only with respect to claims under Part A. See 456 U.S. at 207-208. "In the context of the statute's precisely drawn provisions" and supporting legislative history, the Court explained, the omission of an express provision for judicial review of Part B "amount determinations" furnished "persuasive evidence that Congress deliberately intended to foreclose further review" of such determinations. *Id.* at 208. Thus, even though treating the Medicare program's review provisions as exclusive in *Erika* rendered the administrative determination at issue there completely unreviewable, the Court held them to be exclusive.

More recently, in *Heckler v. Ringer*, 466 U.S. 602 (1984), this Court once again concluded that 42 U.S.C. 405(g) provides the exclusive mechanism for obtaining judicial review of the Secretary's implementation and enforcement of the Medicare Act. In *Ringer*, one of the named plaintiffs, Freeman Ringer, sought to challenge an agency rule that precluded reimbursement for an operation he wished to undergo. Because Ringer had not undergone that procedure, he could not file a claim for reimbursement and challenge the Secretary's decision denying the claim under 42 U.S.C. 405(g). Accordingly, he brought a "pre-enforcement" action in district court requesting a declaratory judgment that the pertinent Medicare regulation was invalid.

466 U.S. at 621-623. This Court held that the Medicare Act itself, in 42 U.S.C. 405(g) (as incorporated by 42 U.S.C. 1395ff(b)), affords the exclusive basis for obtaining jurisdiction over such a claim, and that federal courts could not exercise jurisdiction under 28 U.S.C. 1331. The Court stated: "The third sentence of 42 U.S.C. § 405(h), made applicable to the Medicare Act by 42 U.S.C. § 1395ii, provides that § 405(g), to the exclusion of 28 U.S.C. § 1331, is the sole avenue for judicial review for all 'claim[s] arising under' the Medicare Act." 466 U.S. at 614-615 (emphasis added; footnote omitted).

Finally, just last Term, in *Your Home Visiting Nurse Services, Inc. v. Shalala*, 119 S. Ct. 930, 935 (1999), this Court reaffirmed its holding in *Ringer*, again declining to permit judicial review of claims under the Medicare program except as provided in the Act itself. There, a provider sought judicial review of a refusal to reopen its reimbursement claim. "[J]udicial review under the federal-question statute, 28 U.S.C. § 1331," the Court explained, "is precluded by 42 U.S.C. § 405(h), applicable to the Medicare Act by operation of § 1395ii, which provides that '[n]o action against . . . the [Secretary] or any officer or employee thereof shall be brought under section 1331 . . . of title 28 to recover on any claim arising under this subchapter.'" 119 S. Ct. at 935. The provider's claim, the Court further concluded, "'arises under' the Medicare Act within the meaning of [Section 405(h)] because 'both the standing and the substantive basis for the presentation' of the claim are the Medicare Act." *Ibid.* (quoting *Ringer*, 466 U.S. at 615 (some internal quotation marks omitted)).

3. The exclusivity of the review procedures established by Section 405(g) is further reinforced by the Administrative Procedure Act (APA), 5 U.S.C. 702-704. Section 10(b) of the APA states that, where Congress has provided a "special statutory review proceeding relevant to the subject matter," complainants must use that "form of proceeding for judicial

review," unless it is "inadequa[te]." 5 U.S.C. 703. Moreover, Section 10(c) of the APA bars resort to its general provisions for judicial review of agency action unless "there is no other adequate remedy in a court." 5 U.S.C. 704.

As Attorney General Clark explained shortly after the APA's enactment, "[t]he net effect [of Section 10], clearly intended by the Congress, is to provide for a dovetailing of the general provisions of the [APA] with the particular statutory provisions which the Congress has moulded for special situations." *Attorney General's Manual on the Administrative Procedure Act* 95 (1947).¹⁷ The APA thus "does not provide additional judicial remedies in situations where the Congress has provided special and adequate review procedures." *Bowen v. Massachusetts*, 487 U.S. 879, 903 (1988) (quoting *Attorney General's Manual, supra*, at 101).

4. The foregoing principles foreclose respondent's suit here. Respondent seeks to challenge the Secretary's regulations and guidelines governing the enforcement of Medicare's health, safety, and quality-of-care requirements for nursing homes. But respondent does not seek review of a specific, concrete "determination" or application of those regulations. See J.A. 22 (¶ 16) (Respondent "does not challenge the specific application of the 1995 Regulations and the SOM to any one facility, but challenges instead their lawfulness and their use" generally). Nor does respondent assert that jurisdiction is proper under the mechanisms for judicial review provided by the Medicare Act itself. To the contrary, respondent omits any reference to those provisions in its complaint, relying only on the more general jurisdictional grants contained in 28 U.S.C. 1331 and 1346. J.A. 22 (¶ 14).

Respondent thus is attempting to bypass the express statutory mechanisms for judicial review provided by the

¹⁷ The Court has accorded the *Attorney General's Manual* deference in construing the APA. See, e.g., *Darby v. Cisneros*, 509 U.S. 137, 148 n.10 (1993).

Medicare Act. But such a bypass is precisely what Section 405(h) prohibits, for it makes Section "405(g) * * * the sole avenue for judicial review for all 'claim[s] arising under' the Medicare Act." *Ringer*, 466 U.S. at 615 (emphasis added). Respondent nowhere disputes that its claims "arise under" the Act within the meaning of Section 405(h).¹⁸

Permitting respondent to bypass the mechanisms for review provided by the Medicare Act in this case, moreover, would give rise to the very dangers that the Medicare Act seeks to avoid. Because respondent seeks to raise its claims in the abstract rather than in connection with a specific application of the regulations, "the scope of the controversy" has not been "reduced to more manageable proportions," *Lujan*, 497 U.S. at 891; instead, it remains unwieldy and unmanageable, a broad-ranging attack on virtually every aspect of the Secretary's compliance regime. The correspondingly broad relief respondent seeks also creates a serious risk that premature judicial interference could have devastating consequences for the program. In essence, respondent asks the district court to invalidate the Secretary's entire compliance enforcement program, J.A. 51 (¶¶ A-D), and to bar the Secretary from assessing civil

¹⁸ Indeed, respondent concedes that its "claims on behalf of its Medicare members arise under * * * the provisions of the Social Security Act pertaining to Medicare, 42 U.S.C. § 1395 et seq." J.A. 22 (¶ 14). Respondent's standing, which derives from its members' participation in the Medicare program, clearly derives from the Act; absent the Act, respondent would have no complaint and no basis for bringing suit. See *Salfi*, 422 U.S. at 760-761. Likewise, the "substantive basis for the presentation" of respondent's claims originates in the Act. Respondent, by this lawsuit, seeks to bar the Secretary from enforcing regulations alleged to be inconsistent with the Act, to prevent the Secretary from cutting off reimbursement otherwise provided by the Act, and to bar the imposition of remedies alleged to be contrary to the Act. J.A. 51-53 (¶¶ A-H). To suggest that such an action "does not arise under the Act" is "to ignore both the language and the substance of the complaint and the judgment" that respondent seeks. *Salfi*, 422 U.S. at 761.

penalties, withholding payments, or imposing other sanctions, even where blatant and dangerous violations of the program's health, safety, and quality-of-care criteria are detected, J.A. 52 (¶¶ F-H). That relief would deprive the Secretary of access to the very remedies Congress thought necessary when it enacted OBRA to reform enforcement in 1987, and would bring enforcement to a virtual standstill in Illinois. See pp. 6-9, *supra*. Requiring respondent's members to challenge a discrete instance of enforcement of the regulations under the Medicare Act's review provisions will dramatically reduce the risk of such a grave intrusion on a federal program critical to the health of thousands of Medicare beneficiaries. See *Ringer*, 466 U.S. at 627 (Medicare Act remedies protect the agency from the "potential for overly casual * * * judicial intervention in" important administrative processes); *Salfi*, 422 U.S. at 765 (review mechanisms avoid "premature interference with agency processes, so that the agency may function efficiently").

Likewise, because respondent's challenge is purely anticipatory, it suffers from the absence of a factual record and concrete context that would make it fit for judicial review. Indeed, for that reason, the court of appeals held that respondent's void-for-vagueness claim was not "ripe" under ordinary APA principles. See Pet. App. 10a-11a. Compare *Salfi*, 422 U.S. at 765 (administrative process helps create a record and thereby render the case "fit" for judicial review); *Ringer*, 466 U.S. at 619 (similar). A similar absence of requisite facts—such as the nature of the nursing patient interests at stake in individual cases, e.g., whether there is immediate jeopardy to their lives requiring prompt action—makes adjudication of respondent's procedural due process claims cumbersome, if not impossible, as well. J.A. 32-46 (¶¶ 51-63).

Nor can it be claimed that there is a need here for immediate review outside of ordinary processes. Respondent does not assert that its members are required by allegedly improper regulations to refrain from engaging in otherwise

lawful conduct. Cf. *Lujan*, 497 U.S. at 891 (rules requiring the complainant "to adjust [its] conduct immediately" may be ripe). To the contrary, respondent disavows any challenge to the substantive health, safety, and quality-of-care standards that govern its members' day-to-day operations. Instead, respondent claims that its members cannot tell *what sanction*, if any, otherwise clearly proscribed conduct will draw. See pp. 11-12, *supra*. Such an argument hardly provides compelling grounds for bypassing the express post-enforcement review process provided by the Medicare Act. Would-be criminals normally cannot bring declaratory judgment actions seeking to halt enforcement of criminal laws simply because they cannot tell in advance what their sentence will be if they commit a crime; any arbitrariness in sentencing must be raised through ordinary criminal processes only after an allegedly arbitrary sentence is imposed. The same should be true of would-be violators of the (unchallenged) substantive health, safety, and quality-of-care requirements that protect Medicare beneficiaries from abuse and injury.

B. MICHIGAN ACADEMY DOES NOT PERMIT FEDERAL COURTS TO EXERCISE GENERAL FEDERAL-QUESTION JURISDICTION OVER RESPONDENT'S SUIT

The court of appeals disputed none of the preceding analysis. Nowhere did the court dispute that the text, structure, purposes and legislative history of the Medicare Act all demonstrate that, where the Act provides a mechanism for obtaining judicial review, that mechanism is exclusive. Nor did the court of appeals express any doubt that respondent's members would be able to obtain judicial review of their claims—in a concrete factual setting—through the procedures provided by the Medicare Act itself. Indeed, the court of appeals agreed that, in a long line of cases stretching from *Salfi* to *Ringer*, this Court has rejected efforts to bypass the

mechanisms for judicial review provided by the Medicare Act, and has held that 42 U.S.C. 405(h) precludes federal courts from exercising jurisdiction with respect to such claims under 28 U.S.C. 1331. See Pet. App. 2a-3a.

1. Nonetheless, the court of appeals concluded that *Michigan Academy* allowed the district court to exercise jurisdiction over respondent's pre-enforcement action. In *Michigan Academy*, the plaintiffs challenged the validity of reimbursement regulations under Part B of the Medicare program. At that time, the relevant provision of the Medicare Act, 42 U.S.C. 1395ff(b)(1) (1982), expressly provided for judicial review of disputes concerning the "amount" of reimbursement (if any) payable under Part A, but not under Part B. See 476 U.S. at 674-675. And in *Erika*, the Court had held that that omission, together with the relevant legislative history, established that Congress had intended to preclude judicial review of Part B claims challenging the amount of reimbursement. See 456 U.S. at 207-208.

In *Michigan Academy*, the government argued that Congress's failure to include a provision for judicial review of Part B claims, other than those relating to basic eligibility under the program, indicated that Congress intended to preclude judicial review of *all* issues under Part B except those relating to eligibility. Relying on the "strong presumption that Congress did not mean to prohibit all judicial review" of agency decisions, 476 U.S. at 672, the Court rejected that argument. While the Court found evidence that Congress had deliberately foreclosed any challenge to the amount of benefits awarded in a particular case, it found no evidence that Congress intended to preclude more general "challenges mounted against the *method* by which [the] amounts [of Part B benefits] are to be determined rather than [challenges to] the [amount] *determinations* themselves." *Id.* at 675. In particular, the legislative history provided "specific evidence of Congress' intent to foreclose review" with respect to "amount determinations," i.e., claims concerning the mone-

tary sum of benefits due, but provided no indication of a similar intent to foreclose judicial review of more general "methodology" claims, which might involve "statutory and constitutional challenges to the Secretary's administration of Part B of the Medicare program." *Id.* at 680. Because the government had not produced "clear and convincing evidence" sufficient to overcome the "strong presumption that Congress did not mean to preclude judicial review" entirely, *id.* at 681, the Court held that "methodology" claims were not precluded even though "amount" claims were.

In this case, the court of appeals read *Michigan Academy* as broadly "hold[ing] that [42 U.S.C.] § 1395ii," which incorporates 42 U.S.C. 405(h) into the Medicare program, "does not foreclose Medicare providers' anticipatory challenge[s] to implementing regulations" under 28 U.S.C. 1331. Pet. App. 4a, 6a. In particular, the court of appeals interpreted *Michigan Academy* as holding that Section 405(h) "addresses only 'amount determinations' * * * —that is, calculations of reimbursements." Pet. App. 4a; see also *id.* at 6a. Thus, in the court of appeals' view, pre-enforcement challenges are permissible under *Michigan Academy* whether or not such claims could be adjudicated after a final administrative decision under the mechanisms for judicial review provided by the Medicare Act itself. That reading of *Michigan Academy* is incorrect.

a. Whatever the continuing vitality of *Michigan Academy* in the particular context in which it arose, in light of later amendments to the Medicare Act (see pp. 36-37, *infra*), that decision has no bearing where, as here, the question is not *whether* judicial review will be available, but *when* it will be available. See *National Kidney Patients Ass'n v. Sullivan*, 958 F.2d 1127, 1133 (D.C. Cir. 1992) ("[T]he Court in *Michigan Academy* was concerned not with timing, but with reviewability *vel non*."), cert. denied, 506 U.S. 1049 (1993). The Court's reasoning in *Michigan Academy* literally begins with, 476 U.S. at 670, ends with, *id.* at 681, and is steeped

throughout with, see *id.* at 672, the presumption that Congress intends judicial review to be available. See also *id.* at 681 n.12 (noting that finding review to be available “avoids the ‘serious constitutional question’ that would arise if [the Court] construed § 1395ii to deny a judicial forum for constitutional claims arising under Part B”). That presumption, however, is not “implicate[d]” where, as here, the Medicare Act itself provides for judicial review of a regulation once it is applied in a concrete, factual context. See *Thunder Basin*, 510 U.S. at 207 n.8, 212-214 (“Because court of appeals review is available, this case does not implicate the strong presumption that Congress did not mean to prohibit all judicial review. *Bowen v. Michigan Academy.*”); *MCorp*, 502 U.S. at 44 n.16 (similar analysis). See also *McNary v. Haitian Refugee Ctr., Inc.*, 498 U.S. 479, 498 (1991) (“Inherent in our [*Michigan Academy*] analysis was the concern that * * * [there] would be ‘no review at all of substantial statutory and constitutional challenges to the Secretary’s administration of Part B of the Medicare program.’”) (quoting *Michigan Academy*, 476 U.S. at 680).

Moreover, *Michigan Academy* relied heavily on the legislative history of the relevant statutory provision, which provided “specific evidence” that Congress intended to foreclose judicial review entirely only with respect to so-called “amount” determinations under Part B. 476 U.S. at 680. But whether or not Congress intended judicial review to be *available* at all for *Part B* benefit “amount” determinations has no bearing on the question here, which is merely the *timing* of judicial review of nursing home regulations under *Part A*. The relevant legislative history in this context, moreover, makes it abundantly clear that, while Congress did not intend to foreclose judicial review of claims like respondent’s entirely, it did intend that such review would occur exclusively through the post-enforcement mechanisms provided in the Medicare Act itself. Immediately after describing the mechanisms for judicial review provided by the

Medicare Act, the Senate Report states: “It is intended that the remedies provided by these review procedures shall be exclusive.” S. Rep. No. 404, *supra*, Pt. 1, at 55.

Finally, the distinction between post-decision “amount” claims on the one hand and pre-enforcement actions on the other has no logical place in the context of enforcement actions under 42 U.S.C. 1395cc(h). The Court’s opinion in *Michigan Academy* drew that distinction based on the language of 42 U.S.C. 1395ff (1982), which addressed review of “amount” claims under Part A, but was (at that time) silent about review of such claims under Part B. 476 U.S. at 674-675. Here, the relevant provision of the Medicare Act is not 42 U.S.C. 1395ff, but 42 U.S.C. 1395cc(h), which incorporates 42 U.S.C. 405(b) and (g). Unlike Section 1395ff, Section 1395cc(h) does not mention “amount” claims, and in fact it does not deal with reimbursement requests or such “amount” claims at all. Instead, it addresses challenges to noncompliance determinations. (Reimbursement or “amount” claims relating to nursing facilities would arise instead under 42 U.S.C. 1395oo.) It simply makes no sense to incorporate an amount/methodology distinction from *Michigan Academy* into Section 1395cc(h), which deals with neither reimbursement amounts nor the method by which they are calculated.

Thus, neither *Michigan Academy*’s reasoning, nor the statutory language and legislative history it cited, has any bearing on cases like this one, in which barring review under 28 U.S.C. 1331 would not preclude judicial review altogether, but rather would channel it through the specific mechanisms provided by the Medicare Act. It therefore should be unsurprising that every court of appeals to have considered the matter—with the exception of the panel decision below—has concluded that *Michigan Academy* does not permit pre-enforcement judicial review under 28 U.S.C. 1331 where the Medicare Act itself provides for post-enforcement review. See, e.g., *National Kidney Patients Ass’n*, 958 F.2d

at 1133 (because *Michigan Academy* rested “largely on the presumption of reviewability,” it does not govern where agency action “will not go unreviewed,” but review instead “simply awaits *initial* administrative determination in a concrete setting”); *St. Francis Med. Ctr. v. Shalala*, 32 F.3d 805, 812 (3d Cir. 1994) (“Since a provider seeking Part A payments has these avenues of review available under the Medicare Act, the presumption that Congress did not intend to foreclose judicial review, which was central to the decision in *Michigan Academy*, is inapplicable.”), cert. denied, 514 U.S. 1016 (1995); *Michigan Ass’n of Homes & Servs. for the Aging, Inc. v. Shalala*, 127 F.3d 496, 501 (6th Cir. 1997) (*Michigan Academy* permits review despite 405(h) “when there is no other avenue of judicial review.”).

b. Reading *Michigan Academy* as the court of appeals did here—as drawing a program-wide distinction between pre-enforcement suits challenging regulations on the one hand, and suits seeking to challenge “amount” determinations on the other—would also place *Michigan Academy* in irreconcilable conflict with the Court’s prior decision in *Ringer*, which held that “§ 405(g), to the exclusion of 28 U.S.C. § 1331, is the sole avenue for judicial review for all ‘claim[s] arising under’ the Medicare Act.” *Ringer*, 466 U.S. at 615 (emphasis added). As we have pointed out above (see pp. 24-25, *supra*), one of the named plaintiffs in *Ringer* sought pre-decisional, declaratory relief with respect to a Medicare rule. Moreover, the plaintiff in *Ringer* did not challenge a determination concerning the “amount” of reimbursement (if any) he was due for a particular claim. Instead, he sought to challenge a rule that, if he had submitted a claim, might have required denial of that claim. See 466 U.S. at 613. The Court nevertheless held that Section 405(h) precluded the exercise of general federal-question jurisdiction over such a pre-enforcement challenge. The Court reached an identical result in *Salfi*. There, the plaintiffs sought injunctive relief prohibiting the Secretary

from relying on allegedly unconstitutional provisions (App. at 12-13, *Weinberger v. Salfi*, 422 U.S. 439 (1975) (No. 74-214)). But the Court held that Section 405(h) precluded federal district courts from entertaining their challenges under 28 U.S.C. 1331, and required that they instead file a claim and seek review through the mechanisms provided by the Social Security Act itself. 422 U.S. at 764.

Consequently, if the court of appeals’ construction of *Michigan Academy* were correct—that it limits Section 405(h)’s preclusive effect to “amount” determinations and prevents its application to pre-enforcement regulatory challenges—then *Michigan Academy* would have overruled *Ringer* and *Salfi* *sub silentio*. That reading, we submit, is implausible given the seminal and far-reaching significance of *Salfi* and *Ringer*, as well as the strong presumption, rooted in considerations of stare decisis, that where this Court intends to overrule precedents it says so expressly. See *Rodriguez de Quijas v. Shearson/American Express, Inc.*, 490 U.S. 477, 484 (1989); *Agostini v. Felton*, 521 U.S. 203, 237 (1997). For the same reason, the courts of appeals have uniformly refused to conclude that *Michigan Academy* overruled *Ringer* and *Salfi*. Instead, they have concluded that *Michigan Academy* controls over *Ringer* and *Salfi* only where—unlike here—the Medicare statute itself provides no mechanism for judicial review and, as a result, applying 42 U.S.C. 405(h) to bar suit under 28 U.S.C. 1331 would preclude judicial review altogether. *National Kidney Patients Ass’n*, 958 F.2d at 1132; *Farkas*, 24 F.3d at 860; *American Academy of Dermatology*, 118 F.3d at 1500.¹⁹

¹⁹ The court of appeals likewise erred in asserting that *McNary v. Haitian Refugee Center*, 498 U.S. 479, 497-498 (1991), “reiterated [the] conclusion that § 1395ii [which incorporates Section 405(h)] does not affect regulatory challenges that are detached from any request for reimbursement.” Pet. App. 5a. *McNary* was not a Medicare case; it concerned whether Congress intended to foreclose judicial review of certain claims concerning the immigration status of agricultural workers. In addressing

c. For similar reasons, subsequent statutory amendments have eliminated the basis for continuing application of the result in *Michigan Academy* even in the specific context in which it arose: challenges to the methods used to calculate the amount of reimbursement due on claims under Part B of the Medicare program. As the district court explained below, Pet. App. 18a, Congress amended Section 1395ff in 1986 (months after *Michigan Academy* was decided) to provide for administrative and judicial review (under 42 U.S.C. 405(b) and (g)) of carrier determinations concerning “amount” determinations under Part B. Pub. L. No. 99-509, § 9341(a)(1)(B), 100 Stat. 2037. In light of that amendment and its legislative history, the courts of appeals have uniformly agreed that district courts now lack jurisdiction under 28 U.S.C. 1331 to review all benefit-related claims arising under Part B, including the type of “methodology” disputes at issue in *Michigan Academy*. Instead, all such claims, like their counterparts under Part A, must be brought through the review mechanisms provided by the Medicare Act itself. See *National Kidney Patients Ass’n*, 958 F.2d at 1132 (“[T]he special treatment of part B [methodology claims], based on the pre-October 1986 statutory

that issue, *McNary* cited *Michigan Academy* for the proposition that statutes barring review of a final administrative decision are not sufficient to preclude “collateral” challenges to regulations that would otherwise be unreviewable. Thus, far from supporting the court of appeals’ view that *Michigan Academy* sanctions immediate review of pre-enforcement claims without regard to whether review would be available after exhaustion of administrative remedies, *McNary* stressed the difference between *postponement* of judicial review and *foreclosure*, and noted that the distinction is central to *Michigan Academy*’s holding. “Inherent in our [*Michigan Academy*] analysis,” the *McNary* Court explained, “was the concern that absent such a construction of the judicial review provisions of the Medicare statute, there would be ‘no review at all of substantial statutory and constitutional challenges to the Secretary’s administration of Part B of the Medicare program.’” 498 U.S. at 498 (quoting *Michigan Academy*, 476 U.S. at 680).

differences, cannot survive the elimination of those differences.”); *American Academy of Dermatology*, 118 F.3d at 1500 (“[T]he amount/methodology distinction established in *Michigan Academy* is no longer viable.”); *Martin v. Shalala*, 63 F.3d 497, 503 (7th Cir. 1995) (“[T]he *Michigan Academy* distinctions drawn between ‘amount of payment’ and ‘validity of the statute and regulations’ challenges are no longer meaningful or necessary.”); *Farkas*, 24 F.3d at 860 (amount/methodology distinction no longer “good law”); *Abbey v. Sullivan*, 978 F.2d 37, 42 (2d Cir. 1992) (*Michigan Academy*’s distinction “relegat[ed] to irrelevancy”).

2. Although conceding the lack of “practical support” for the result it reached, Pet. App. 5a, the court of appeals nonetheless read Part III of the Court’s opinion in *Michigan Academy*—the only portion addressed to 42 U.S.C. 1395ii, which incorporates 42 U.S.C. 405(h) into the Medicare program—as providing a broadly applicable limit on the preclusive scope of Section 405(h). In particular, the court of appeals interpreted Part III as holding that Section 405(h), as incorporated into Medicare, precludes review of “only ‘amount determinations.’” Pet. App. 6a. That reasoning is flawed from premise to conclusion.

As an initial matter, the construction of Sections 1395ii and 405(h) the court of appeals purported to draw from *Michigan Academy* is not supported by that decision. This Court did not hold that Section 405(h) has no effect on any claim other than one involving the amount of reimbursement. Rather, again relying on the presumption that Congress intends agency action to be reviewable, 476 U.S. at 680, 681, the Court simply rejected the “extreme position” that Congress, by incorporating 42 U.S.C. 405(h) into the Medicare Act, “intended no review at all of substantial statutory and constitutional challenges to the Secretary’s administration of Part B of the Medicare program.” 476 U.S. at 680. Nowhere did the Court reject the distinctly more moderate position that, in those circumstances where the

Medicare Act does provide mechanisms for judicial review, Section 405(h) channels all challenges to the Secretary's actions through those mechanisms.

In fact, far from offering a broadly applicable construction of Section 405(h), the Court in *Michigan Academy* expressly declined to "pass on the meaning of § 405(h) in the abstract," instead choosing to decide only that Section 405(h) "d[id] not apply" to preclude review of the particular claims at issue there. And to the extent the Court did identify generally applicable constructions of Section 405(h), both of the constructions it identified would bar the pre-enforcement action respondent seeks to bring here. The broader of the two interpretations (which represented the government's position in that case) was that Section 405(h) "by its terms prevents any resort to the grant of general federal-question jurisdiction contained in 28 U.S.C. 1331." 476 U.S. at 679. That construction would surely bar respondent's claim, which rests explicitly on 28 U.S.C. 1331. The narrower view identified by the Court was that Congress enacted Section 405(h) "to make clear that whatever specific procedures it provided for judicial review of final action by the Secretary were exclusive, and could not be circumvented by resort to the general jurisdiction of the federal courts." 476 U.S. at 679. That position too—although previously rejected by this Court in *Salfi* as excessively narrow²⁰—would bar respondent's suit here, since the issues respondent seeks to raise on behalf of its members all may be raised after enforcement action is taken against a member, under the "specific procedures * * * for judicial review" provided by the Medicare Act.

²⁰ "Nor can it be argued that the third sentence of § 405(h) simply serves to prevent a bypass of the § 405(g) requirements by filing a district court complaint alleging entitlement prior to applying for benefits through administrative channels." *Salfi*, 422 U.S. at 759 n.6.

3. Nor does the court of appeals' decision find support in the text of 42 U.S.C. 405(h). The court of appeals found it significant that the third sentence of 42 U.S.C. 405(h) bars the exercise of general federal-question jurisdiction over suits "to recover" on a claim arising under the Medicare Act, apparently reading "to recover" as meaning to obtain a monetary recovery. See Pet. App. 6a. That reasoning, however, does not take respondent's suit outside of Section 405(h).

a. To begin with, the court of appeals' reading of the phrase "to recover" is unnecessarily starchy. "Section 405(h) does not apply on its own terms" to challenges to the Secretary's enforcement of health, safety and quality-of-care requirements, "but instead is incorporated *mutatis mutandis*"—that is, with necessary changes in details and meaning, *Black's Law Dictionary* 1019 (6th ed. 1990)—"by § 1395ii." *Michigan Academy*, 476 U.S. at 680. In legal contexts, moreover, the phrase "to recover" does not refer only to the recovery of a monetary award. Instead, it means "to prevail" or "to obtain relief." See *Black's Law Dictionary* 1275-1276 (6th ed. 1990) ("In a narrower sense, to be successful in a suit, * * * to have judgment, to obtain a favorable or final judgment."); *Webster's Third New International Dictionary* 1898 (1981) ("to gain by legal process; to obtain a final judgment in one's favor: to succeed in a lawsuit or proceeding"); *Random House Dictionary of the English Language* 1613 (2d ed. 1987) ("to obtain by judgment in a court of law or by legal proceedings").

That Congress used the words "to recover" in that broader sense in Section 405(h)—and did not by that phrase intend to limit Section 405(h)'s application to "amount" determinations—is evident from the fact that Congress incorporated Section 405(h) into numerous parts of the Medicare program where "amount" determinations, as such, do not arise. For example, Congress expressly incorporated Section 405(h) into 42 U.S.C. 1320a-7 and 1320c-5, which address

the circumstances under which Medicare providers can or must be excluded from the program. See 42 U.S.C. 1320a-7(f)(3). Since neither of those provisions deals with “amount” determinations—instead, like 42 U.S.C. 1395cc(h) here, they deal with eligibility to participate in Medicare—it would be illogical to construe Section 405(h) as “affect[ing]” only “amount determinations” of claims for reimbursement. Congress cannot be presumed to have specifically incorporated Section 405(h) in that setting with the understanding that so doing would have no effect at all.²¹

Construing Section 405(h) as “affect[ing]” only ‘amount determinations,’ Pet. App. 6a, moreover, would make the second sentence in Section 405(h) mere surplusage. An amount determination is by its very nature a reimbursement decision by the Secretary. Judicial review of such amount determinations through means other than those provided by the Medicare Act itself, however, is already precluded by the second sentence of Section 405(h), which states that “[n]o * * * decision of the [Secretary] shall be reviewed by any person, tribunal, or governmental agency except as herein provided.” The court of appeals’ construction thus makes the third sentence of Section 405(h) superfluous in light of the second sentence.

The court of appeals’ ruling ignores the text and purpose of the second sentence of Section 405(h) in another respect as well. Whatever the words “to recover” might mean in the

²¹ That Congress specifically meant Section 405(h) to apply to suits, like respondent’s, that seek to avoid sanctions is also made clear by its incorporation into 42 U.S.C. 1320a-7a and 1320a-8, which authorize the Secretary to impose civil money penalties and other sanctions for misconduct. See 42 U.S.C. 1320a-7(f)(3) (“The provisions of section 405(h) * * * shall apply with respect to sections 1320a-7a [and] 1320a-8.”). Under the court of appeals’ theory, Section 405(h) in that context would not bar an anticipatory suit seeking to prevent the Secretary from collecting a civil penalty, since such a suit would not be an “amount” claim seeking reimbursement from the Secretary, but rather a pre-enforcement suit.

third sentence of Section 405(h), those words do not appear in the second sentence, which bars “any person, tribunal or governmental agency” from reviewing *any* “decision” of the Secretary, except as provided in the Medicare Act.²²

b. In any event, respondent’s suit is a suit “to recover” under Medicare even if some nexus to monetary recovery were necessary to trigger Section 405(h). By this suit, respondent seeks to preclude enforcement of the requirements that govern its members’ participation in Medicare, and thus their eligibility for payment. See 42 U.S.C. 1395i-3(a) to (d); 42 C.F.R. 483.1-483.75; pp. 2, 12, *supra*. Respondent even prays for an injunction prohibiting the Secretary from imposing “upon [respondent’s] Medicare members any ban on payment as a remedy for any deficiency.” J.A. 52 (¶¶G, H). As the district court aptly observed (Pet. App. 17a):

²² The Secretary’s regulations and guidelines are not themselves “decisions” of the Secretary within the meaning of the second sentence of 42 U.S.C. 405(h). See *Michigan Academy*, 476 U.S. at 679 n.8. But respondent cannot avoid the force of Section 405(h)’s second sentence by arguing that it is not challenging a “decision” of the Secretary here. If that argument were accepted, any plaintiff could bypass the Medicare Act’s exhaustion requirements at will by filing a declaratory judgment action in federal court at a time when its claims are least ripe for review—when enforcement may not even be contemplated and the Secretary therefore has not yet issued any “decision.” For the same reason, this Court rejected that argument in *Ringer*, 466 U.S. at 621. There, the lead plaintiff contended that Section 405(h) did not preclude his lawsuit because his request had neither “blossomed into a ‘claim’ cognizable under § 405(g),” nor resulted in a decision by the Secretary. The Court held that to allow plaintiffs “to bypass the exhaustion requirements of the Medicare Act by simply bringing declaratory judgment actions in federal court” in any instance where the Secretary has not yet issued an individualized decision would “undercut Congress’ carefully crafted scheme for administering the Medicare Act.” See 466 U.S. at 621. Accordingly, it held that Ringer’s claim was barred even though the regulation he sought to challenge had not yet resulted in a “decision” by the Secretary on a claim for benefits.

[A]t the heart of [respondent's] case, is a claim for benefits. This is evidenced by the relief sought by [respondent]. [Respondent] seeks continuation of Medicare payments and reimbursement for past due payments incurred by the patients at the nursing homes. Thus, the issue here is whether or not the nursing homes are entitled to benefits.

For that reason, respondent's claim is essentially indistinguishable from the lead plaintiff's claim in *Ringer* and *Salfi*. Just as Freeman Ringer sought to bring a pre-enforcement challenge to the Secretary's rule barring payment for the treatment he wanted, *Ringer*, 466 U.S. at 614-615, respondent here brought a pre-enforcement challenge to regulations that could deny payments to its members if noncompliance is found. See p. 41, *supra*. And just as *Salfi* sought (as an alternative to monetary relief) a declaratory judgment that the statutory provisions were unconstitutional and injunctive relief prohibiting the Secretary from applying those provisions to deny him payment in administrative proceedings (App. at 12-13, *Weinberger v. Salfi, supra*), respondent makes an identical request with respect to the regulations at issue here. Since Ringer's and Salfi's anticipatory lawsuits challenging payment-barring statutes and regulations under 28 U.S.C. 1331 were precluded by Section 405(h) as suits "to recover on a claim arising under" the Act, respondent's action must be barred by Section 405(h) as well.²³

²³ To the extent there are differences between *Ringer* and this case, *Ringer* provided the more compelling case for bypass of administrative remedies. The lead plaintiff in *Ringer* wished to undergo surgery that, under the Secretary's guidelines, was not covered by Medicare. Because Ringer allegedly could not afford to pay for the surgery himself and (he contended) no surgeon would perform the surgery in light of the non-coverage guideline, Ringer contended that he could not have the surgery, submit a claim, and challenge the Secretary's resulting decision through the Medicare Act's judicial review procedures; instead, to have the surgery, he needed an anticipatory ruling. See 466 U.S. at 629 (Stevens,

Even as an original matter, moreover, the court of appeals' theory would place an implausible gloss on the statutory scheme as a whole. It ignores the fact that Congress deliberately paired Section 405(g) with Section 405(h), with the obvious purpose of excluding through the latter, at a minimum, all issues that could be raised under the former. And it turns the normal priorities for access to judicial review on their head. Under the court of appeals' approach, the party with the least need for immediate access to judicial review—the party bringing an abstract, facial challenge to regulations that may not be applied to it—has immediate access to the courts, while the party with a greater need, i.e., a party to whom the regulations have actually been applied and that is facing imminent enforcement proceedings and remedies, cannot bring suit until it exhausts administrative remedies. It is singularly unlikely that Congress intended to allocate access to the courts in that manner.

C. RESPONDENT'S CLAIMS CONCERNING THE ADEQUACY OF THE MEDICARE ACT'S REVIEW MECHANISMS ARE WITHOUT MERIT

In its brief in opposition, respondent attempted to defend the judgment of the court of appeals on different grounds. In particular, respondent argued that the issues it sought to raise in district court do not fall within Section 405(h)'s preclusive scope because they would not be addressed in a hearing under 42 U.S.C. 405(b); given that no such hearing is available, respondent argued, providing judicial review only after exhaustion of administrative remedies "is the practical equivalent of total denial of judicial review." See Br. in Opp. 13; see also *id.* at 9-10. The court of appeals did not address those arguments, and they are, in any event, without merit.

1. Respondent is, as an initial matter, incorrect in asserting that its members can obtain no relief at all with re-

J., dissenting). Respondent's institutional members could not make any such assertion of personal hardship.

spect to any of its claims. For example, respondent contends that the State Operations Manual, which is used by survey agencies when reviewing nursing facilities for compliance, is invalid because it was “promulgated without the required notice and comment procedures required by the Administrative Procedures Act for substantive regulations.” J.A. 18, 27-28, 46 (¶ 3A, 32-36, 94A-94B); see Br. in Opp. 2. Any nursing facility that is subjected to a remedy for a violation because of the Manual, however, can challenge the finding of a violation in administrative proceedings. Because ALJs and the Departmental Appeals Board are not bound by the Manual, see *Shalala v. Guernsey Mem'l Hosp.*, 514 U.S. 87, 99 (1995),²⁴ such a nursing home could obtain complete relief. Moreover, a claim of a violation of the APA’s notice-and-comment requirements can in any event be addressed on judicial review, after exhaustion, under 42 U.S.C. 405(g). See *Ringer*, 466 U.S. at 614-616 (claim that regulations and instructions to intermediaries violate APA notice-and-comment requirements reviewable under Section 405(g) after exhaustion of administrative remedies).²⁵

To be sure, some of the other issues respondent seeks to raise, such as its constitutional contentions and its challenges to the Secretary’s regulations, ordinarily would not be the

²⁴ See, e.g., *Furlong v. Shalala*, 156 F.3d 384, 388-389, 394 (2d Cir. 1998) (noting that ALJs had, in over 100 cases, declined to apply a particular manual provision); see also *Ringer*, 466 U.S. at 607-608 (even though HCFA had concluded that a particular surgical procedure was not “reasonable and necessary” within the meaning of the Medicare Act and had issued instructions to fiscal intermediaries not to approve claims for that procedure, ALJs “were consistently ruling in favor of individual * * * claimants” with respect to that procedure; only later did HCFA issue a formal ruling that bound ALJs).

²⁵ Of course, interpretive rules, general statements of policy, and rules of agency organization, procedure, or practice in the Manual are exempt from APA notice-and-comment requirements. 5 U.S.C. 553(b)(A); *Guernsey Mem'l Hosp.*, 514 U.S. at 99.

subject of an administrative hearing. Neither the Departmental Appeals Board nor individual ALJs are free to depart from statutory and regulatory requirements. But that does not mean that Section 405(h) ceases to apply. To the contrary, Section 405(h) requires all claims “arising under” the Medicare Act to be brought through the mechanisms provided by the Medicare Act itself; nowhere does it exclude individual issues that would not be addressed in the administrative process. That, in fact, is precisely the holding of *Salfi*, 422 U.S. at 760-762. There, the plaintiffs sought to challenge the constitutionality of a provision of the Social Security Act, a challenge that could not be resolved in the administrative process. This Court held that the language of Section 405(h), “which is sweeping and direct,” does not limit its preclusive effect “to decisions of the Secretary on issues of law or fact. Rather, it extends to any ‘action’ seeking ‘to recover on any * * * claim’—irrespective of whether resort to judicial processes is necessitated by discretionary decisions of the Secretary or by * * * nondiscretionary application of allegedly unconstitutional statutory restrictions.” *Id.* at 757, 762. As the Court summarized: “[T]he plain words of the third sentence of § 405(h) do not preclude constitutional challenges. They simply require that [the challenges] be brought under jurisdictional grants contained in the Act, and thus in conformity with the same standards which are applicable to nonconstitutional claims arising under the Act.” *Id.* at 762.

This Court likewise has applied Section 405(h) to preclude federal courts from exercising federal-question jurisdiction over procedural and due process claims like respondent’s. In *Ringer*, for example, the Court “disagree[d] in particular with [the court of appeals’] apparent conclusion that simply because a claim somehow can be construed as ‘procedural,’ it is cognizable in federal district court by way of federal-question jurisdiction.” 466 U.S. at 614. Instead, “the inquiry in determining whether § 405(h) bars federal-question jurisdic-

tion must be whether the claim ‘arises under’ the Act, not whether it lends itself to a ‘substantive’ rather than a ‘procedural’ label.” *Id.* at 615.

Finally, in *Mathews v. Eldridge*, 424 U.S. 319 (1976), the plaintiff alleged that the procedures the Secretary employed under the Act violated procedural due process. Even though the plaintiff’s claims were “collateral” to the merits—they challenged the process provided, not the substantive result—and the plaintiff made a colorable claim that the post-deprivation review provided through administrative remedies would be inadequate, this Court held that “[t]he only avenue for judicial review” of such claims “is 42 U.S.C. 405(g).” *Id.* at 327. Section 405(g), the Court explained, permits adequate review of even completely collateral claims so long as the “final decision” requirement is properly applied.²⁶

²⁶ The Court held that the “final decision” requirement of Section 405(g)—like the “final decision” requirement of 28 U.S.C. 1291—is sufficiently flexible to permit expedited review of collateral claims in limited, appropriate circumstances. According to the Court, an otherwise interim decision by the Secretary may be considered “final” within the meaning of Section 405(g) and thus immediately reviewable, even where the plaintiff has not fully pursued all administrative remedies, if: (1) a claim for benefits has been properly presented to the Secretary, 424 U.S. at 328-329, (2) the challenge on which review is sought is “entirely collateral to” the merits of the plaintiff’s substantive claim, 424 U.S. at 330, and (3) full relief with respect to that challenge could not be afforded after exhaustion of administrative remedies. *Mathews*, 424 U.S. at 331-332. See also *Bowen v. City of New York*, 476 U.S. 467, 483-486 (1986) (excusing failure to exhaust in “unique” circumstances involving secret agency policy).

In *Mathews* itself, the Court held that the plaintiff could seek immediate judicial review under 42 U.S.C. 405(g) to assert a constitutional right to a pre-deprivation hearing, once he had presented his claim to the Secretary and the Secretary had made an initial determination to terminate his benefits without that full hearing, because the plaintiff could not obtain relief on his claim that he had a right to a *pre*-deprivation hearing in an action for judicial review *after* the deprivation had taken effect. 424 U.S. at 331-333. That holding, however, does not assist respondent. First, respondent does not assert that jurisdiction is proper

2. The text and structure of the Medicare Act confirm the correctness of that result. As the Court recognized in *Ringer* and *Salfi*, nothing in Section 405(h) limits its application to issues that might be addressed by an ALJ in the administrative process; its sweeping language instead extends to “all ‘claim[s] arising under’ the Medicare Act.” *Ringer*, 466 U.S. at 615. Nor can such a limit be inferred from the scope of review provided by Section 405(g). Whereas the hearing provided by Section 405(b) might have a limited scope, the review provided by Section 405(g) is not limited to those issues cognizable before an ALJ. For example, far from restricting the reviewing court to an examination of whether “the findings * * * as to any fact” are “supported by substantial evidence,” 42 U.S.C. 405(g), Section 405(g) expressly permits the reviewing court to address “the validity of [the] regulations” themselves, *ibid.*—an issue an ALJ could not address.

Other provisions of the Medicare Act, moreover, confirm that Congress intended to channel all claims through the administrative process as a prerequisite to judicial review under Section 405(g) and parallel Medicare provisions, even where individual legal issues bearing on those claims—

under Section 405(g); it relies on the general federal-question statute, 28 U.S.C. 1331, instead. J.A. 22 (¶ 14); Pet. App. 13a, 15a. Second, the collateral order rule described in *Mathews* excuses the plaintiff from fully pursuing available administrative remedies, but it does not excuse the other jurisdictional prerequisites for review under Sections 405(g) and 1395cc(h), such as the requirement that the plaintiff actually present its claim to the Secretary, see *Salfi*, 422 U.S. at 764; *Ringer*, 466 U.S. at 617-618; *Mathews*, 424 U.S. at 328, and that it be “dissatisfied with a determination” of the Secretary, 42 U.S.C. 405(g), 1395cc(h)(2). Here, the district court expressly found that respondent “has not alleged or shown any attempt at presentation of [its] claims to the Secretary,” *id.* at 19a, and respondent has never challenged that finding. That failure is fatal to jurisdiction under 42 U.S.C. 405(g), since the requirements of presentation and dissatisfaction with a determination are not waivable. See *Ringer*, 466 U.S. at 617.

including challenges to the Act or regulations—would not be addressed in the administrative process. For example, 42 U.S.C. 1395oo(f)(1) permits the Provider Reimbursement Review Board (PRRB) to facilitate judicial review on an expedited basis by certifying “that it is without authority to decide” a “question of law or regulations relevant to the matters in controversy.” Once such a certification is made in a case otherwise properly before the PRRB, 42 U.S.C. 1395oo(a), an action for judicial review on that question may be filed immediately; it need not await the PRRB’s resolution of issues that are within its competence to decide, as would otherwise be required by *Salfi* and *Ringer*. See 42 U.S.C. 1395oo(f)(1); *Bethesda Hosp. Ass’n v. Bowen*, 485 U.S. 399, 406-407 (1988). If matters outside the PRRB’s competence to decide were not required to be channeled into the special statutory procedure for administrative and judicial review together with issues that are—and such issues instead could be presented outside that procedure in district court under 28 U.S.C. 1331—the expedited review provision in 42 U.S.C. 1395oo(f)(1) would be entirely unnecessary. It is, of course, inappropriate to construe a statute so as to make any of its provisions superfluous. *Moskal v. United States*, 498 U.S. 103, 109-110 (1990). Similarly, in the case of individuals who seek administrative and judicial review of individual benefit claims under 42 U.S.C. 1395ff(b) (which incorporates 42 U.S.C. 405(g)), the Act specifically contemplates that judicial review of national coverage determinations of general applicability will be available under 42 U.S.C. 405(g), even though such determinations cannot be reviewed by an ALJ. See 42 U.S.C. 1395ff(b)(3).²⁷

²⁷ See also 42 U.S.C. 1395ff(b)(4) (barring judicial review of a regulation or instruction relating to a method of determining the amount of payments under Part B if the regulation or instruction was issued prior to January 1, 1981). Judicial review similarly would be available with respect to the Secretary’s choice of remedies to be imposed on a particular facility,

3. Because even issues that would not be addressed in a hearing can be reviewed by a court under 42 U.S.C. 405(g) after exhaustion, respondent’s reliance on *Thunder Basin*, 510 U.S. at 207, is misplaced. Quoting *Thunder Basin*, respondent notes that whether “a statute is intended to preclude initial judicial review” depends in part on “whether the claims can be afforded meaningful review” through the mechanisms provided by statute. Br. in Opp. 13. Respondent then contends that the issues it seeks to raise “cannot be meaningfully addressed or reviewed in the administrative process.” Br. in Opp. 13. But the question is not whether its contentions will be “meaningfully addressed * * * in the administrative process.” It is whether they will be meaningfully addressed through the statutory mechanism for administrative and judicial review as a whole, with an emphasis on the latter. See 510 U.S. at 212-213 (inquiry particularly important “where a finding of preclusion could foreclose all meaningful judicial review”) (emphasis added). In fact, in *Thunder Basin* itself, this Court held that the statutory review mechanism was meaningful, adequate, and exclusive “[e]ven if” the administrative agency would not or

and the characterization of seriousness of violations to the extent it influenced the choice of remedies, even though those issues are, by regulation, outside the scope of ALJ and Departmental Appeals Board review. (The ALJ, of course is not precluded from addressing whether and how many violations occurred.) See 42 C.F.R. 498.3(d)(10)-(11) (excluding the choice of remedy and disputes concerning the agency’s characterization of the scope and severity of the violations from the administrative review process, except where the range of civil money penalties would be affected). The standard of review applied to such remedy-related claims, however, is extraordinarily deferential. See *Butz v. Glover Livestock Comm’n Co.*, 411 U.S. 182, 185-186 (1973) (“[W]here Congress has entrusted an administrative agency with the responsibility of selecting the means of achieving the statutory policy ‘the relation of remedy to policy is peculiarly a matter for administrative competence,’ and the agency’s choice of remedies may not be overturned unless ‘unwarranted in law or * * * without justification in fact.’”).

could not adjudicate the statutory and constitutional claims at issue there, because those issues ultimately would "be meaningfully addressed" on judicial review. *Id.* at 215. The same is true of the issues respondent seeks to raise here.

4. At bottom, respondent's suit for anticipatory relief is nothing more than an effort to bypass the reticulated mechanisms for administrative and judicial review provided by the Medicare Act itself. Seeking to avoid the necessity of bringing challenges in the context of specific violations, and attempting to evade the requirements that individual claims be presented to the Secretary and administrative remedies be exhausted, respondent filed the current facial challenge to the Secretary's regulations in an effort to obtain far-reaching and intrusive relief. But it was precisely such circumvention of the statutory processes (and the resulting potential for unnecessary and damaging intrusion into the administration of programs affecting millions of people) that this Court rejected in *Salfi*, in *Mathews*, and in *Ringer*, and that Sections 405(g) and 405(h) were designed to prevent. Those provisions simply do not permit a nursing facility to split off one legal issue bearing on the merits of a challenge to a compliance determination and present that issue in an independent action for declaratory or injunctive relief under 28 U.S.C. 1331. Of course, "[i]n the best of all worlds, immediate judicial access * * * might be desirable" for particular challenges in particular cases. *Ringer*, 466 U.S. at 627. But this is not such a case and, even if it were, "Congress, in § 405(g) and § 405(h), struck a different balance, refusing declaratory relief and requiring that administrative remedies be exhausted before judicial review of the Secretary's decisions takes place." *Ibid.* Because the court of appeals' judgment fails to respect that statutory balance, it should be reversed.

CONCLUSION

The judgment of the court of appeals should be reversed.

Respectfully submitted.

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APPENDIX A

STATUTORY PROVISIONS

1. Section 405(g) of Title 42, United States Code, provides:

(g) Judicial review

Any individual, after any final decision of the Commissioner of Social Security made after a hearing to which he was a party, irrespective of the amount in controversy, may obtain a review of such decision by a civil action commenced within sixty days after the mailing to him of notice of such decision or within such further time as the Commissioner of Social Security may allow. Such action shall be brought in the district court of the United States for the judicial district in which the plaintiff resides, or has his principal place of business, or, if he does not reside or have his principal place of business within any such judicial district, in the United States District Court for the District of Columbia. As part of the Commissioner's answer the Commissioner of Social Security shall file a certified copy of the transcript of the record including the evidence upon which the findings and decision complained of are based. The court shall have power to enter, upon the pleadings and transcript of the record, a judgment affirming, modifying, or reversing the decision of the Commissioner of Social Security, with or without remanding the cause for a rehearing. The findings of the Commissioner of Social Security as to any fact, if supported by substantial evidence, shall be conclusive, and where a claim has been denied by the Commissioner of Social Security or a decision is rendered under subsection (b) of this section which is adverse to an individual who was a party to the hearing before the Commissioner of Social Security, because of failure of the claimant or such individual

to submit proof in conformity with any regulation prescribed under subsection (a) of this section, the court shall review only the question of conformity with such regulations and the validity of such regulations. The court may, on motion of the Commissioner of Social Security made for good cause shown before the Commissioner files the Commissioner's answer, remand the case to the Commissioner of Social Security for further action by the Commissioner of Social Security, and it may at any time order additional evidence to be taken before the Commissioner of Social Security, but only upon a showing that there is new evidence which is material and that there is good cause for the failure to incorporate such evidence into the record in a prior proceeding; and the Commissioner of Social Security shall, after the case is remanded, and after hearing such additional evidence if so ordered, modify or affirm the Commissioner's findings of fact or the Commissioner's decision, or both, and shall file with the court any such additional and modified findings of fact and decision, and a transcript of the additional record and testimony upon which the Commissioner's action in modifying or affirming was based. Such additional or modified findings of fact and decision shall be reviewable only to the extent provided for review of the original findings of fact and decision. The judgment of the court shall be final except that it shall be subject to review in the same manner as a judgment in other civil actions. Any action instituted in accordance with this subsection shall survive notwithstanding any change in the person occupying the office of Commissioner of Social Security or any vacancy in such office.

2. Section 405(h) of Title 42, United States Code, provides:

(h) Finality of Commissioner's decision

The findings and decision of the Commissioner of Social Security after a hearing shall be binding upon all individuals who were parties to such hearing. No findings of fact or decision of the Commissioner of Social Security shall be reviewed by any person, tribunal, or governmental agency except as herein provided. No action against the United States, the Commissioner of Social Security, or any officer or employee thereof shall be brought under section 1331 or 1346 of title 28 to recover on any claim arising under this subchapter.

3. Section 1320a-7 of Title 42, United States Code, provides in relevant part:

§ 1320a-7. Exclusion of certain individuals and entities from participation in Medicare and State health care programs

(a) Mandatory exclusion

The Secretary shall exclude the following individuals and entities from participation in any program under subchapter XVIII of this chapter and shall direct that the following individuals and entities be excluded from participation in any State health care program (as defined in subsection (h) of this section):

(1) Conviction of program-related crimes

* * * * *

(2) Conviction relating to patient abuse

* * * * *

(b) Permissive exclusion

The Secretary may exclude the following individuals and entities from participation in any program under subchapter XVIII of this chapter and may direct that the following individuals and entities be excluded from participation in any State health care program:

(1) Conviction relating to fraud

* * * * *

(2) Conviction relating to obstruction of an investigation

* * * * *

(3) Conviction relating to controlled substance

* * * * *

(f) Notice, hearing, and judicial review

(1) Subject to paragraph (2), any individual or entity that is excluded (or directed to be excluded) from participation under this section is entitled to reasonable notice and opportunity for a hearing thereon by the Secretary to the same extent as is provided in section 405(b) of this title, and to judicial review of the Secretary's final decision after such hearing as is provided in section 405(g) of this title, except that, in so applying such sections and section 405(l) of this title, any reference therein to the Commissioner of Social Security or the Social Security Administration shall be considered a reference to the Secretary or the Department of Health and Human Services, respectively.

(2) Unless the Secretary determines that the health or safety of individuals receiving services warrants the exclusion taking effect earlier, any individual or entity that is the subject of an adverse determination under subsection (b)(7) of this section shall be entitled to a hearing by an administrative law judge (as provided under section 405(b) of this title) on the determination under subsection (b)(7) of this section before any exclusion based upon the determination takes effect.

(3) The provisions of section 405(h) of this title shall apply with respect to this section and sections 1320a-7a, 1320a-8, and 1320c-5 of this title to the same extent as it is applicable with respect to subchapter II of this chapter, except that, in so applying such section and section 405(l) of this title, any reference therein to the Commissioner of Social Security shall be considered a reference to the Secretary.

4. Section 1320a-7a of Title 42, United States Code, provides in relevant part:

§ 1320a-7a. Civil monetary penalties

* * * *

(e) **Initiation of proceeding; authorization by Attorney General, notice, etc., estoppel, failure to comply with order or procedure**

* * * *

(2) The Secretary shall not make a determination adverse to any person under subsection (a) or (b) of this section until the person has been given written notice and an opportunity for the determination to be made on the record after a hearing at which the person is entitled to be represented by counsel, to present witnesses, and to cross-examine witnesses against the person.

* * * *

(e) Review by courts of appeals

Any person adversely affected by a determination of the Secretary under this section may obtain a review of such determination in the United States Court of Appeals for the circuit in which the person resides, or in which the claim was presented, by filing in such court (within sixty days following the date the person is notified of the Secretary's determination) a written petition requesting that the determination be modified or set aside. A copy of the petition shall be forthwith transmitted by the clerk of the court to the Secretary, and thereupon the Secretary shall file in the Court^[1] the record in the proceeding as provided in section 2112 of title 28. Upon such filing, the court shall have

jurisdiction of the proceeding and of the question determined therein, and shall have the power to make and enter upon the pleadings, testimony, and proceedings set forth in such record a decree affirming, modifying, remanding for further consideration, or setting aside, in whole or in part, the determination of the Secretary and enforcing the same to the extent that such order is affirmed or modified. No objection that has not been urged before the Secretary shall be considered by the court, unless the failure or neglect to urge such objection shall be excused because of extraordinary circumstances. The findings of the Secretary with respect to questions of fact, if supported by substantial evidence on the record considered as a whole, shall be conclusive. If any party shall apply to the court for leave to adduce additional evidence and shall show to the satisfaction of the court that such additional evidence is material and that there were reasonable grounds for the failure to adduce such evidence in the hearing before the Secretary, the court may order such additional evidence to be taken before the Secretary and to be made a part of the record. The Secretary may modify his findings as to the facts, or make new findings, by reason of additional evidence so taken and filed, and he shall file with the court such modified or new findings, which findings with respect to questions of fact, if supported by substantial evidence on the record considered as a whole, shall be conclusive, and his recommendations, if any, for the modification or setting aside of his original order. Upon the filing of the record with it, the jurisdiction of the court shall be exclusive and its judgment and decree shall be final, except that the same shall be subject to review by the Supreme Court of the United States, as provided in section 1254 of title 28.

[1] So in original. Probably should not be capitalized.

5. Section 1395i-3(h) of Title 42, United States Code, provides:

(h) Enforcement process

(1) In general

If a State finds, on the basis of a standard, extended, or partial extended survey under subsection (g)(2) of this section or otherwise, that a skilled nursing facility no longer meets a requirement of subsection (b), (c), or (d) of this section, and further finds that the facility's deficiencies—

(A) immediately jeopardize the health or safety of its residents, the State shall recommend to the Secretary that the Secretary take such action as described in paragraph (2)(A)(i); or

(B) do not immediately jeopardize the health or safety of its residents, the State may recommend to the Secretary that the Secretary take such action as described in paragraph (2)(A)(ii).

If a State finds that a skilled nursing facility meets the requirements of subsections (b), (c), and (d) of this section, but, as of a previous period, did not meet such requirements, the State may recommend a civil money penalty under paragraph (2)(B)(ii) for the days in which it finds that the facility was not in compliance with such requirements.

(2) Secretarial authority

(A) In general

With respect to any skilled nursing facility in a State, if the Secretary finds, or pursuant to a recommendation of the State under paragraph (1) finds, that a skilled nursing facility no longer meets a requirement of subsection (b), (c),

(d), or (e) of this section, and further finds that the facility's deficiencies—

(i) immediately jeopardize the health or safety of its residents, the Secretary shall take immediate action to remove the jeopardy and correct the deficiencies through the remedy specified in subparagraph (B)(iii), or terminate the facility's participation under this subchapter and may provide, in addition, for one or more of the other remedies described in subparagraph (B); or

(ii) do not immediately jeopardize the health or safety of its residents, the Secretary may impose any of the remedies described in subparagraph (B).

Nothing in this subparagraph shall be construed as restricting the remedies available to the Secretary to remedy a skilled nursing facility's deficiencies. If the Secretary finds, or pursuant to the recommendation of the State under paragraph (1) finds, that a skilled nursing facility meets such requirements but, as of a previous period, did not meet such requirements, the Secretary may provide for a civil money penalty under subparagraph (B)(ii) for the days on which he finds that the facility was not in compliance with such requirements.

(B) Specified remedies

The Secretary may take the following actions with respect to a finding that a facility has not met an applicable requirement:

(1) Denial of payment

The Secretary may deny any further payments under this subchapter with respect to all individuals entitled to benefits under this subchapter in the facility or with respect to such individuals admitted to the facility after the effective date of the finding.

(ii) Authority with respect to civil money penalties

The Secretary may impose a civil money penalty in an amount not to exceed \$10,000 for each day of noncompliance. The provisions of section 1320a-7a of this title (other than subsections (a) and (b)) shall apply to a civil money penalty under the previous sentence in the same manner as such provisions apply to a penalty or proceeding under section 1320a-7a(a) of this title.

(iii) Appointment of temporary management

In consultation with the State, the Secretary may appoint temporary management to oversee the operation of the facility and to assure the health and safety of the facility's residents, where there is a need for temporary management while—

- (I) there is an orderly closure of the facility, or
- (II) improvements are made in order to bring the facility into compliance with all the requirements of subsections (b), (c), and (d) of this section.

The temporary management under this clause shall not be terminated under subclause (II) until the Secretary has determined that the facility has the management capability to ensure continued compliance with all the requirements of subsections (b), (c), and (d) of this section.

The Secretary shall specify criteria, as to when and how each of such remedies is to be applied, the amounts of any fines, and the severity of each of these remedies, to be used in the imposition of such remedies. Such criteria shall be designed so as to minimize the time between the identification of violations and final imposition of the remedies and shall provide for the imposition of incrementally more severe fines for repeated or uncorrected deficiencies. In addition, the

Secretary may provide for other specified remedies, such as directed plans of correction.

(C) Continuation of payments pending remediation

The Secretary may continue payments, over a period of not longer than 6 months after the effective date of the findings, under this subchapter with respect to a skilled nursing facility not in compliance with a requirement of subsection (b), (c), or (d) of this section, if—

- (i) the State survey agency finds that it is more appropriate to take alternative action to assure compliance of the facility with the requirements than to terminate the certification of the facility,
- (ii) the State has submitted a plan and timetable for corrective action to the Secretary for approval and the Secretary approves the plan of corrective action, and
- (iii) the facility agrees to repay to the Federal Government payments received under this subparagraph if the corrective action is not taken in accordance with the approved plan and timetable.

The Secretary shall establish guidelines for approval of corrective actions requested by States under this subparagraph.

(D) Assuring prompt compliance

If a skilled nursing facility has not complied with any of the requirements of subsections (b), (c), and (d) of this section, within 3 months after the date the facility is found to be out of compliance with such requirements, the Secretary shall impose the remedy described in subparagraph (B)(i) for all individuals who are admitted to the facility after such date.

(E) Repeated noncompliance

In the case of a skilled nursing facility which, on 3 consecutive standard surveys conducted under subsection (g)(2) of this section, has been found to have provided substandard quality of care, the Secretary shall (regardless of what other remedies are provided)—

- (i) impose the remedy described in subparagraph (B)(i), and
- (ii) monitor the facility under subsection (g)(4)(B) of this section,

until the facility has demonstrated, to the satisfaction of the Secretary, that it is in compliance with the requirements of subsections (b), (c), and (d) of this section, and that it will remain in compliance with such requirements.

(3) Effective period of denial of payment

A finding to deny payment under this subsection shall terminate when the Secretary finds that the facility is in substantial compliance with all the requirements of subsections (b), (c), and (d) of this section.

(4) Immediate termination of participation for facility where Secretary finds noncompliance and immediate jeopardy

If the Secretary finds that a skilled nursing facility has not met a requirement of subsection (b), (c), or (d) of this section, and finds that the failure immediately jeopardizes the health or safety of its residents, the Secretary shall take immediate action to remove the jeopardy and correct the deficiencies through the remedy specified in paragraph (2)(B)(iii), or the Secretary shall terminate the facility's participation under this subchapter. If the facility's participation under this subchapter is terminated, the State shall provide for the safe

and orderly transfer of the residents eligible under this subchapter consistent with the requirements of subsection (c)(2) of this section.

(5) Construction

The remedies provided under this subsection are in addition to those otherwise available under State or Federal law and shall not be construed as limiting such other remedies, including any remedy available to an individual at common law. The remedies described in clauses (i),^[2] and (iii) of paragraph (2)(B) may be imposed during the pendency of any hearing.

(6) Sharing of information

Notwithstanding any other provision of law, all information concerning skilled nursing facilities required by this section to be filed with the Secretary or a State agency shall be made available by such facilities to Federal or State employees for purposes consistent with the effective administration of programs established under this subchapter and subchapter XIX of this chapter, including investigations by State medicaid fraud control units.

^[2] So in original. The comma probably should not appear.

6. Section 1395cc of Title 42, United States Code, provides in relevant part:

§ 1395cc. Agreements with providers of services

* * * *

(b) Termination or nonrenewal of agreements

(1) A provider of services may terminate an agreement with the Secretary under this section at such time and upon such notice to the Secretary and the public as may be provided in regulations, except that notice of more than six months shall not be required.

(2) The Secretary may refuse to enter into an agreement under this section or, upon such reasonable notice to the provider and the public as may be specified in regulations, may refuse to renew or may terminate such an agreement after the Secretary—

(A) has determined that the provider fails to comply substantially with the provisions of the agreement, with the provisions of this subchapter and regulations thereunder, or with a corrective action required under section 1395ww(f)(2)(B) of this title,

(B) has determined that the provider fails substantially to meet the applicable provisions of section 1395x of this title, or

(C) has excluded the provider from participation in a program under this subchapter pursuant to section 1320a-7 of this title or section 1320a-7a of this title.

(3) A termination of an agreement or a refusal to renew an agreement under this subsection shall become effective on the same date and in the same manner as an

exclusion from participation under the program under this subchapter becomes effective under section 1320a-7(c) of this title.

* * * *

(h) Dissatisfaction with determination of Secretary; appeal by institutions or agencies; single notice and hearing

(1) Except as provided in paragraph (2), an institution or agency dissatisfied with a determination by the Secretary that it is not a provider of services or with a determination described in subsection (b)(2) of this section shall be entitled to a hearing thereon by the Secretary (after reasonable notice) to the same extent as is provided in section 405(b) of this title, and to judicial review of the Secretary's final decision after such hearing as is provided in section 405(g) of this title, except that, in so applying such sections and in applying section 405(l) of this title thereto, any reference therein to the Commissioner of Social Security or the Social Security Administration shall be considered a reference to the Secretary or the Department of Health and Human Services, respectively.

(2) An institution or agency is not entitled to separate notice and opportunity for a hearing under both section 1320a-7 of this title and this section with respect to a determination or determinations based on the same underlying facts and issues.

7. Section 1395ii of Title 42, United States Code, provides:

§ 1395ii. Application of certain provisions of subchapter II

The provisions of sections 406 and 416(j) of this title, and of subsections (a), (d), (e), (h), (i), (j), (k), and (l) of section 405 of this title, shall also apply with respect to this subchapter to the same extent as they are applicable with respect to subchapter II of this chapter, except that, in applying such provisions with respect to this subchapter, any reference therein to the Commissioner of Social Security or the Social Security Administration shall be considered a reference to the Secretary or the Department of Health and Human Services, respectively.

**APPENDIX B
REGULATORY PROVISIONS**

1. Section 488.301 of Title 42, Code of Federal Regulations, provides:

§ 488.301 Definitions.

As used in this subpart—

Abbreviated standard survey means a survey other than a standard survey that gathers information primarily through resident-centered techniques on facility compliance with the requirements for participation. An abbreviated standard survey may be premised on complaints received; a change of ownership, management, or director of nursing; or other indicators of specific concern.

Abuse means the willful infliction of injury, unreasonable confinement, intimidation, or punishment with resulting physical harm, pain or mental anguish.

Deficiency means a SNF's or NF's failure to meet a participation requirement specified in the Act or in part 483, subpart B of this chapter.

Dually participating facility means a facility that has a provider agreement in both the Medicare and Medicaid programs.

Extended survey means a survey that evaluates additional participation requirements subsequent to finding substandard quality of care during a standard survey.

Facility means a SNF or NF, or a distinct part SNF or NF, in accordance with § 483.5 of this chapter.

Immediate family means husband or wife; natural or adoptive parent, child or sibling; stepparent, stepchild, step-

brother, or stepsister; father-in-law, mother-in-law, son-in-law, daughter-in-law, brother-in-law, or sister-in-law; grandparent or grandchild.

Immediate jeopardy means a situation in which the provider's noncompliance with one or more requirements of participation has caused, or is likely to cause, serious injury, harm, impairment, or death to a resident.

Misappropriation of resident property means the deliberate misplacement, exploitation, or wrongful, temporary or permanent use of a resident's belongings or money without the resident's consent.

Neglect means failure to provide goods and services necessary to avoid physical harm, mental anguish, or mental illness.

Noncompliance means any deficiency that causes a facility to not be in substantial compliance.

Nurse aide means an individual, as defined in § 483.75(e)(1) of this chapter.

Nursing facility (NF) means a Medicaid nursing facility.

Partial extended survey means a survey that evaluates additional participation requirements subsequent to finding substandard quality of care during an abbreviated standard survey.

Skilled nursing facility (SNF) means a Medicare nursing facility.

Standard survey means a periodic, resident-centered inspection which gathers information about the quality of

service furnished in a facility to determine compliance with the requirements for participation.

Substandard quality of care means one or more deficiencies related to participation requirements under § 483.13, Resident behavior and facility practices, § 483.15, Quality of life, or § 483.25, Quality of care of this chapter, which constitute either immediate jeopardy to resident health or safety; a pattern of or widespread actual harm that is not immediate jeopardy; or a widespread potential for more than minimal harm, but less than immediate jeopardy, with no actual harm.

Substantial compliance means a level of compliance with the requirements of participation such that any identified deficiencies pose no greater risk to resident health or safety than the potential for causing minimal harm.

Validation survey means a survey conducted by the Secretary within 2 months following a standard survey, abbreviated standard survey, partial extended survey, or extended survey for the purpose of monitoring State survey agency performance.

2. Section 488.330 of Title 42, Code of Federal Regulations, provides:

§ 488.330 Certification of compliance or non-compliance.

(a) *General rules—(1) Responsibility for certification.*

(i) The State survey agency surveys all facilities for compliance or noncompliance with requirements for long term care facilities. The survey by the State survey agency may be followed by a Federal validation survey.

(A) The State certifies the compliance or noncompliance of non-State operated NFs. Regardless of the State entity doing the certification, it is final, except in the case of a complaint or validation survey conducted by HCFA, or HCFA review of the State's findings.

(B) HCFA certifies the compliance or noncompliance of all State-operated facilities.

(C) The State survey agency certifies the compliance or noncompliance of a non-State operated SNF, subject to the approval of HCFA.

(D) The State survey agency certifies compliance or noncompliance for a dually participating SNF/NF. In the case of a disagreement between HCFA and the State survey agency, a finding of noncompliance takes precedence over that of compliance.

(ii) In the case of a validation survey, the Secretary's determination as to the facility's noncompliance is binding, and takes precedence over a certification of compliance resulting from the State survey.

(2) *Basis for certification.* (i) Certification by the State is based on the survey agency findings.

(ii) Certification by HCFA is based on either the survey agency findings (in the case of State-operated facilities), or, in the case of a validation survey, on HCFA's own survey findings.

(b) *Effect of certification—(1) Certification of compliance.* A certification of compliance constitutes a determination that the facility is in substantial compliance and is eligible to participate in Medicaid as a NF, or in Medicare as a SNF, or in Medicare and Medicaid as a dually participating facility.

(2) *Certification of noncompliance.* A certification of noncompliance requires denial of participation for prospective providers and enforcement action for current providers in accordance with subpart F of this part. Enforcement action must include one of the following:

(i) Termination of any Medicare or Medicaid provider agreements that are in effect.

(ii) Application of alternative remedies instead of, or in addition to, termination procedures.

(c) *Notice of certification of noncompliance and resulting action.* The notice of certification of noncompliance is sent in accordance with the timeframes specified in § 488.402(f), and resulting action is issued by HCFA, except when the State is taking the action for a non-State operated NF.

(d) *Content of notice of certification of noncompliance.* The notice of certification of noncompliance is sent in accordance with the timeframes specified in § 488.402(f) and includes information on all of the following:

- (1) Nature of noncompliance.
- (2) Any alternative remedies to be imposed under subpart F of this part.
- (3) Any termination or denial of participation action to be taken under this part.
- (4) The appeal rights available to the facility under this part.
- (5) Timeframes to be met by the provider and certifying agency with regard to each of the enforcement actions or appeal procedures addressed in the notice.
- (e) *Appeals.* (1) Notwithstanding any provision of State law, the State must impose remedies promptly on any provider of services participating in the Medicaid program—
 - (i) After promptly notifying the facility of the deficiencies and impending remedy or remedies; and
 - (ii) Except for civil money penalties, during any pending hearing that may be requested by the provider of services.
 (2) HCFA imposes remedies promptly on any provider of services participating in the Medicare or Medicaid program or any provider of services participating in both the Medicare and Medicaid programs—
 - (i) After promptly notifying the facility of the deficiencies and impending remedy or remedies; and

(ii) Except for civil money penalties, during any pending hearing that may be requested by the provider of services.

(3) The provisions of part 498 of this chapter apply when the following providers request a hearing on a denial of participation, or certification of noncompliance leading to an enforcement remedy (including termination of the provider agreement), except State monitoring:

- (i) All State-operated facilities;
- (ii) SNFs and dually participating SNF/NFs; and
- (iii) Any other facilities subject to a HCFA validation survey or HCFA review of the State's findings.

(4) The provisions of part 431 of this chapter apply when a non-State operated Medicaid NF, which has not received a HCFA validation survey or HCFA review of the State's findings, requests a hearing on the State's denial of participation, termination of provider agreement, or certification of noncompliance leading to an alternative remedy, except State monitoring.

(f) *Provider agreements.* HCFA or the Medicaid agency may execute a provider agreement when a prospective provider is in substantial compliance with all the requirements for participation for a SNF or NF, respectively.

(g) *Special rules for Federal validation surveys.* (1) HCFA may make independent certifications of a NF's, SNF's, or dually participating facility's noncompliance based on a HCFA validation survey.

(2) HCFA issues the notice of actions affecting facilities for which HCFA did validation surveys.

(3) For non-State-operated NFs and non-State-operated dually participating facilities, any disagreement between HCFA and the State regarding the timing and choice of remedies is resolved in accordance with § 488.452.

(4) Either HCFA or the survey agency, at HCFA's option, may revisit the facility to ensure that corrections are made.

3. Section 488.331 of Title 42, Code of Federal Regulations, provides:

§ 488.331 Informal dispute resolution.

(a) *Opportunity to refute survey findings.* (1) For non-Federal surveys, the State must offer a facility an informal opportunity, at the facility's request, to dispute survey findings upon the facility's receipt of the official statement of deficiencies.

(2) For Federal surveys, HCFA offers a facility an informal opportunity, at the facility's request, to dispute survey findings upon the facility's receipt of the official statement of deficiencies.

(b)(1) Failure of the State or HCFA, as appropriate, to complete informal dispute resolution timely cannot delay the effective date of any enforcement action against the facility.

(2) A facility may not seek a delay of any enforcement action against it on the grounds that informal dispute resolution has not been completed before the effective date of the enforcement action.

(c) If a provider is subsequently successful, during the informal dispute resolution process, at demonstrating that deficiencies should not have been cited, the deficiencies are removed from the statement of deficiencies and any enforcement actions imposed solely as a result of those cited deficiencies are rescinded.

(d) *Notification.* Upon request, HCFA does and the State must provide the facility with written notification of the informal dispute resolution process.

4. Subpart F (Sections 488.400-488.456) of Title 42, Code of Federal Regulations, provides:

Subpart F—Enforcement of Compliance for Long-Term Care Facilities with Deficiencies

SOURCE: 59 FR 56243, Nov. 10, 1994, unless otherwise noted.

§ 488.400 Statutory basis.

Sections 1819(h) and 1919(h) of the Act specify remedies that may be used by the Secretary or the State respectively when a SNF or a NF is not in substantial compliance with the requirements for participation in the Medicare and Medicaid programs. These sections also provide for ensuring prompt compliance and specify that these remedies are in addition to any others available under State or Federal law, and, except for civil money penalties, are imposed prior to the conduct of a hearing.

§ 488.401 Definitions.

As used in this subpart—

New admission means a resident who is admitted to the facility on or after the effective date of a denial of payment remedy and, if previously admitted, has been discharged before that effective date. Residents admitted before the effective date of the denial of payment, and taking temporary leave, are not considered new admissions, nor subject to the denial of payment.

Plan of correction means a plan developed by the facility and approved by HCFA or the survey agency that describes the actions the facility will take to correct deficiencies and specifies the date by which those deficiencies will be corrected.

[59 FR 56243, Nov. 10, 1994; 60 FR 50118, Sept. 28, 1995]

§ 488.402 General provisions.

(a) *Purpose of remedies.* The purpose of remedies is to ensure prompt compliance with program requirements.

(b) *Basis for imposition and duration of remedies.* When HCFA or the State chooses to apply one or more remedies specified in § 488.406, the remedies are applied on the basis of noncompliance found during surveys conducted by HCFA or by the survey agency.

(c) *Number of remedies.* HCFA or the State may apply one or more remedies for each deficiency constituting noncompliance or for all deficiencies constituting noncompliance.

(d) *Plan of correction requirement.* (1) Except as specified in paragraph (d)(2) of this section, regardless of which remedy is applied, each facility that has deficiencies with respect to program requirements must submit a plan of correction for approval by HCFA or the survey agency.

(2) *Isolated deficiencies.* A facility is not required to submit a plan of correction when it has deficiencies that are isolated and have a potential for minimal harm, but no actual harm has occurred.

(e) *Disagreement regarding remedies.* If the State and HCFA disagree on the decision to impose a remedy, the disagreement is resolved in accordance with § 488.452.

(f) *Notification requirements—*(1) Except when the State is taking action against a non-State operated NF, HCFA or the State (as authorized by HCFA) gives the provider notice of the remedy, including the—

(i) Nature of the noncompliance;

- (ii) Which remedy is imposed;
- (iii) Effective date of the remedy; and
- (iv) Right to appeal the determination leading to the remedy.

(2) When a State is taking action against a non-State operated NF, the State's notice must include the same information required by HCFA in paragraph (f)(1) of this section.

(3) *Immediate jeopardy—2 day notice.* Except for civil money penalties and State monitoring imposed when there is immediate jeopardy, for all remedies specified in § 488.406 imposed when there is immediate jeopardy, the notice must be given at least 2 calendar days before the effective date of the enforcement action.

(4) *No immediate jeopardy—15 day notice.* Except for civil money penalties and State monitoring, notice must be given at least 15 calendar days before the effective date of the enforcement action in situations in which there is no immediate jeopardy.

(5) *Latest date of enforcement action.* The 2 and 15-day notice periods begin when the facility receives the notice, but, in no event will the effective date of the enforcement action be later than 20 calendar days after the notice is sent.

(6) *Civil money penalties.* For civil money penalties, the notices must be given in accordance with the provisions of §§ 488.434 and 488.440.

(7) *State monitoring.* For State monitoring, no prior notice is required.

[59 FR 56243, Nov. 10, 1994; 60 FR 50118, Sept. 28, 1995]

§ 488.404 Factors to be considered in selecting remedies.

- (a) *Initial assessment.* In order to select the appropriate remedy, if any, to apply to a facility with deficiencies, HCFA and the State determine the seriousness of the deficiencies.
- (b) *Determining seriousness of deficiencies.* To determine the seriousness of the deficiency, HCFA considers and the State must consider at least the following factors:
 - (1) Whether a facility's deficiencies constitute—
 - (i) No actual harm with a potential for minimal harm;
 - (ii) No actual harm with a potential for more than minimal harm, but not immediate jeopardy;
 - (iii) Actual harm that is not immediate jeopardy; or
 - (iv) Immediate jeopardy to resident health or safety.
 - (2) Whether the deficiencies—
 - (i) Are isolated;
 - (ii) Constitute a pattern; or
 - (iii) Are widespread.
 - (c) *Other factors which may be considered in choosing a remedy within a remedy category.* Following the initial assessment, HCFA and the State may consider other factors, which may include, but are not limited to the following:
 - (1) The relationship of the one deficiency to other deficiencies resulting in noncompliance.

(2) The facility's prior history of noncompliance in general and specifically with reference to the cited deficiencies.

§ 488.406 Available remedies.

(a) *General.* In addition to the remedy of termination of the provider agreement, the following remedies are available:

- (1) Temporary management.
- (2) Denial of payment including—
 - (i) Denial of payment for all individuals, imposed by HCFA, to a—
 - (A) Skilled nursing facility, for Medicare;
 - (B) State, for Medicaid; or
 - (ii) Denial of payment for all new admissions.
 - (3) Civil money penalties.
 - (4) State monitoring.
 - (5) Transfer of residents.
 - (6) Closure of the facility and transfer of residents.
 - (7) Directed plan of correction.
 - (8) Directed in-service training.
 - (9) Alternative or additional State remedies approved by HCFA.

(b) *Remedies that must be established.* At a minimum, and in addition to termination of the provider agreement, the

State must establish the following remedies or approved alternatives to the following remedies:

- (1) Temporary management.
- (2) Denial of payment for new admissions.
- (3) Civil money penalties.
- (4) Transfer of residents.
- (5) Closure of the facility and transfer of residents.
- (6) State monitoring.
- (c) *State plan requirement.* If a State wishes to use remedies for noncompliance that are either additional or alternative to those specified in paragraphs (a) or (b) of this section, it must—
 - (1) Specify those remedies in the State plan; and
 - (2) Demonstrate to HCFA's satisfaction that those remedies are as effective as the remedies listed in paragraph (a) of this section, for deterring noncompliance and correcting deficiencies.
- (d) *State remedies in dually participating facilities.* If the State's remedy is unique to the State plan and has been approved by HCFA, then that remedy, as imposed by the State under its Medicaid authority, may be imposed by HCFA against the Medicare provider agreement of a dually participating facility.

[59 FR 56243, Nov. 10, 1994; 60 FR 50118, Sept. 28, 1995]

§ 488.408 Selection of remedies.

(a) *Categories of remedies.* In this section, the remedies specified in § 488.406(a) are grouped into categories and applied to deficiencies according to how serious the non-compliance is.

(b) *Application of remedies.* After considering the factors specified in § 488.404, as applicable, if HCFA and the State choose to impose remedies, as provided in paragraphs (c)(1), (d)(1) and (e)(1) of this section, for facility noncompliance, instead of, or in addition to, termination of the provider agreement, HCFA does and the State must follow the criteria set forth in paragraphs (c)(2), (d)(2), and (e)(2) of this section, as applicable.

(c) *Category 1.* (1) Category 1 remedies include the following:

- (i) Directed plan of correction.
- (ii) State monitoring.
- (iii) Directed in-service training.

(2) HCFA does or the State must apply one or more of the remedies in Category 1 when there—

(i) Are isolated deficiencies that constitute no actual harm with a potential for more than minimal harm but not immediate jeopardy; or

(ii) Is a pattern of deficiencies that constitutes no actual harm with a potential for more than minimal harm but not immediate jeopardy.

(3) Except when the facility is in substantial compliance, HCFA or the State may apply one or more of the remedies in Category 1 to any deficiency.

(d) *Category 2.* (1) Category 2 remedies include the following:

- (i) Denial of payment for new admissions.
- (ii) Denial of payment for all individuals imposed only by HCFA.

(iii) Civil money penalties of \$50-3,000 per day.

(2) HCFA applies one or more of the remedies in Category 2, or, except for denial of payment for all individuals, the State must apply one or more of the remedies in Category 2 when there are—

(i) Widespread deficiencies that constitute no actual harm with a potential for more than minimal harm but not immediate jeopardy; or

(ii) One or more deficiencies that constitute actual harm that is not immediate jeopardy.

(3) HCFA or the State may apply one or more of the remedies in Category 2 to any deficiency except when—

(i) The facility is in substantial compliance; or

(ii) HCFA or the State imposes a civil money penalty for a deficiency that constitutes immediate jeopardy, the penalty must be in the upper range of penalty amounts, as specified in § 488.438(a).

(e) *Category 3.* (1) Category 3 remedies include the following:

- (i) Temporary management.
- (ii) Immediate termination.
- (iii) Civil money penalties of \$3,050-\$10,000 per day.
- (2) When there are one or more deficiencies that constitute immediate jeopardy to resident health or safety—
 - (i) HCFA does and the State must do one or both of the following:
 - (A) Impose temporary management; or
 - (B) Terminate the provider agreement;
 - (ii) HCFA and the State may impose a civil money penalty of \$3,050-\$10,000 per day, in addition to imposing the remedies specified in paragraph (e)(2)(i) of this section.
- (3) When there are widespread deficiencies that constitute actual harm that is not immediate jeopardy, HCFA and the State may impose temporary management, in addition to Category 2 remedies.
- (f) *Plan of correction.* (1) Except as specified in paragraph (f)(2) of this section, each facility that has a deficiency with regard to a requirement for long term care facilities must submit a plan of correction for approval by HCFA or the State, regardless of—
 - (i) Which remedies are imposed; or
 - (ii) The seriousness of the deficiencies.
- (2) When there are only isolated deficiencies that HCFA or the State determines constitute no actual harm

with a potential for minimal harm, the facility need not submit a plan of correction.

(g) *Appeal of a certification of noncompliance.* (1) A facility may appeal a certification of noncompliance leading to an enforcement remedy.

(2) A facility may not appeal the choice of remedy, including the factors considered by HCFA or the State in selecting the remedy, specified in § 488.404.

[59 FR 56243, Nov. 10, 1994; 60 FR 50118, Sept. 28, 1995]

§ 488.410 Action when there is immediate jeopardy.

(a) If there is immediate jeopardy to resident health or safety, the State must (and HCFA does) either terminate the provider agreement within 23 calendar days of the last date of the survey or appoint a temporary manager to remove the immediate jeopardy. The rules for appointment of a temporary manager in an immediate jeopardy situation are as follows:

(1) HCFA does and the State must notify the facility that a temporary manager is being appointed.

(2) If the facility fails to relinquish control to the temporary manager, HCFA does and the State must terminate the provider agreement within 23 calendar days of the last day of the survey, if the immediate jeopardy is not removed. In these cases, State monitoring may be imposed pending termination.

(3) If the facility relinquishes control to the temporary manager, the State must (and HCFA does) notify the facility that, unless it removes the immediate jeopardy, its provider

agreement will be terminated within 23 calendar days of the last day of the survey.

(4) HCFA does and the State must terminate the provider agreement within 23 calendar days of the last day of survey if the immediate jeopardy has not been removed.

(b) HCFA or the State may also impose other remedies, as appropriate.

(c)(1) In a NF or dually participating facility, if either HCFA or the State finds that a facility's noncompliance poses immediate jeopardy to resident health or safety, HCFA or the State must notify the other of such a finding.

(2) HCFA will or the State must do one or both of the following:

(i) Take immediate action to remove the jeopardy and correct the noncompliance through temporary management.

(ii) Terminate the facility's participation under the State plan. If this is done, HCFA will also terminate the facility's participation in Medicare if it is a dually participating facility.

(d) The State must provide for the safe and orderly transfer of residents when the facility is terminated.

(e) If the immediate jeopardy is also substandard quality of care, the State survey agency must notify attending physicians and the State board responsible for licensing the facility administrator of the finding of substandard quality of care, as specified in § 488.325(h).

[59 FR 56243, Nov. 10, 1994; 60 FR 50118, Sept. 28, 1995]

§ 488.412 Action when there is no immediate jeopardy.

(a) If a facility's deficiencies do not pose immediate jeopardy to residents' health or safety, and the facility is not in substantial compliance, HCFA or the State may terminate the facility's provider agreement or may allow the facility to continue to participate for no longer than 6 months from the last day of the survey if—

(1) The State survey agency finds that it is more appropriate to impose alternative remedies than to terminate the facility's provider agreement;

(2) The State has submitted a plan and timetable for corrective action approved by HCFA; and

(3) The facility in the case of a Medicare SNF or the State in the case of a Medicaid NF agrees to repay to the Federal government payments received after the last day of the survey that first identified the deficiencies if corrective action is not taken in accordance with the approved plan of correction.

(b) If a facility does not meet the criteria for continuation of payment under paragraph (a) of this section, HCFA will and the State must terminate the facility's provider agreement.

(c) HCFA does and the State must deny payment for new admissions when a facility is not in substantial compliance 3 months after the last day of the survey.

(d) HCFA terminates the provider agreement for SNFs and NFs, and stops FFP to a State for a NF for which participation was continued under paragraph (a) of this

section, if the facility is not in substantial compliance within 6 months of the last day of the survey.

[59 FR 56243, Nov. 10, 1994; 60 FR 50118, Sept. 28, 1995]

§ 488.414 Action when there is repeated substandard quality of care.

(a) *General.* If a facility has been found to have provided substandard quality of care on the last three consecutive standard surveys, as defined in § 488.305, regardless of other remedies provided—

(1) HCFA imposes denial of payment for all new admissions, as specified in § 488.417, or denial of all payments, as specified in § 488.418;

(2) The State must impose denial of payment for all new admissions, as specified in § 488.417; and

(3) HCFA does and the State survey agency must impose State monitoring, as specified in § 488.422, until the facility has demonstrated to the satisfaction of HCFA or the State, that it is in substantial compliance with all requirements and will remain in substantial compliance with all requirements.

(b) *Repeated noncompliance.* For purposes of this section, repeated noncompliance is based on the repeated finding of substandard quality of care and not on the basis that the substance of the deficiency or the exact tag number for the deficiency was repeated.

(c) *Standard surveys to which this provision applies.* Standard surveys completed by the State survey agency on or after October 1, 1990, are used to determine whether the threshold of three consecutive standard surveys is met.

(d) *Program participation.* (1) The determination that a certified facility has repeated instances of substandard quality of care is made without regard to any variances in the facility's program participation (that is, any standard survey completed for Medicare, Medicaid or both programs will be considered).

(2) Termination would allow the count of repeated substandard quality of care surveys to start over.

(3) *Change of ownership.* (i) A facility may not avoid a remedy on the basis that it underwent a change of ownership.

(ii) In a facility that has undergone a change of ownership, HCFA does not and the State may not restart the count of repeated substandard quality of care surveys unless the new owner can demonstrate to the satisfaction of HCFA or the State that the poor past performance no longer is a factor due to the change in ownership.

(e) *Facility alleges corrections or achieves compliance after repeated substandard quality of care is identified.* (1) If a penalty is imposed for repeated substandard quality of care, it will continue until the facility has demonstrated to the satisfaction of HCFA or the State that it is in substantial compliance with the requirements and that it will remain in substantial compliance with the requirements for a period of time specified by HCFA or the State.

(2) A facility will not avoid the imposition of remedies or the obligation to demonstrate that it will remain in compliance when it—

(i) Alleges correction of the deficiencies cited in the most recent standard survey; or

- (ii) Achieves compliance before the effective date of the remedies.

§ 488.415 Temporary management.

(a) *Definition.* Temporary management means the temporary appointment by HCFA or the State of a substitute facility manager or administrator with authority to hire, terminate or reassign staff, obligate facility funds, alter facility procedures, and manage the facility to correct deficiencies identified in the facility's operation.

(b) *Qualifications.* The temporary manager must—

(1) Be qualified to oversee correction of deficiencies on the basis of experience and education, as determined by the State;

(2) Not have been found guilty of misconduct by any licensing board or professional society in any State;

(3) Have, or a member of his or her immediate family have, no financial ownership interest in the facility; and

(4) Not currently serve or, within the past 2 years, have served as a member of the staff of the facility.

(c) *Payment of salary.* The temporary manager's salary—

(1) Is paid directly by the facility while the temporary manager is assigned to that facility; and

(2) Must be at least equivalent to the sum of the following—

(i) The prevailing salary paid by providers for positions of this type in what the State considers to be the facility's geographic area;

(ii) Additional costs that would have reasonably been incurred by the provider if such person had been in an employment relationship; and

(iii) Any other costs incurred by such a person in furnishing services under such an arrangement or as otherwise set by the State.

(3) May exceed the amount specified in paragraph (c)(2) of this section if the State is otherwise unable to attract a qualified temporary manager.

(d) *Failure to relinquish authority to temporary management.*—(1) *Termination of provider agreement.* If a facility fails to relinquish authority to the temporary manager as described in this section, HCFA will or the State must terminate the provider agreement in accordance with § 488.456.

(2) *Failure to pay salary of temporary manager.* A facility's failure to pay the salary of the temporary manager is considered a failure to relinquish authority to temporary management.

(e) *Duration of temporary management.* Temporary management ends when the facility meets any of the conditions specified in § 488.454(c).

§ 488.417 Denial of payment for all new admissions.

(a) *Optional denial of payment.* Except as specified in paragraph (b) of this section, HCFA or the State may deny payment for all new admissions when a facility is not in

substantial compliance with the requirements, as defined in § 488.401, as follows:

(1) *Medicare facilities.* In the case of Medicare facilities, HCFA may deny payment to the facility.

(2) *Medicaid facilities.* In the case of Medicaid facilities—

(i) The State may deny payment to the facility; and

(ii) HCFA may deny payment to the State for all new Medicaid admissions to the facility.

(b) *Required denial of payment.* HCFA does or the State must deny payment for all new admissions when—

(1) The facility is not in substantial compliance, as defined in § 488.401, 3 months after the last day of the survey identifying the noncompliance; or

(2) The State survey agency has cited a facility with substandard quality of care on the last three consecutive standard surveys.

(c) *Resumption of payments: Repeated instances of substandard quality of care.* When a facility has repeated instances of substandard quality of care, payments to the facility or, under Medicaid, HCFA payments to the State on behalf of the facility, resume on the date that—

(1) The facility achieves substantial compliance as indicated by a revisit or written credible evidence acceptable to HCFA (for all facilities except non-State operated NFs against which HCFA is imposing no remedies) or the State (for non-State operated NFs against which HCFA is imposing no remedies); and

(2) HCFA (for all facilities except non-State operated NFs against which HCFA is imposing no remedies) or the State (for non-State operated NFs against which HCFA is imposing no remedies) believes that the facility is capable of remaining in substantial compliance.

(d) *Resumption of payments: No repeated instances of substandard quality of care.* When a facility does not have repeated instances of substandard quality of care, payments to the facility or, under Medicaid, HCFA payments to the State on behalf of the facility, resume prospectively on the date that the facility achieves substantial compliance, as indicated by a revisit or written credible evidence acceptable to HCFA (under Medicare) or the State (under Medicaid).

(e) *Restriction.* No payments to a facility or, under Medicaid, HCFA payments to the State on behalf of the facility, are made for the period between the date that the—

(1) Denial of payment remedy is imposed; and

(2) Facility achieves substantial compliance, as determined by HCFA or the State.

[59 FR 56243, Nov. 10, 1994; 60 FR 50119, Sept. 28, 1995]

§ 488.418 Secretarial authority to deny all payments.

(a) *HCFA option to deny all payment.* If a facility has not met a requirement, in addition to the authority to deny payment for all new admissions as specified in § 488.417, HCFA may deny any further payment for all Medicare residents in the facility and to the State for all Medicaid residents in the facility.

(b) *Prospective resumption of payment.* Except as provided in paragraphs (d) and (e) of this section, if the facility achieves substantial compliance, HCFA resumes payment prospectively from the date that it verifies as the date that the facility achieved substantial compliance.

(c) *Restriction on payment after denial of payment is imposed.* If payment to the facility or to the State resumes after denial of payment for all residents, no payment is made for the period between the date that—

(1) Denial of payment was imposed; and

(2) HCFA verifies as the date that the facility achieved substantial compliance.

(d) *Retroactive resumption of payment.* Except when a facility has repeated instances of substandard quality of care, as specified in paragraph (e) of this section, when HCFA or the State finds that the facility was in substantial compliance before the date of the revisit, or before HCFA or the survey agency received credible evidence of such compliance, payment is resumed on the date that substantial compliance was achieved, as determined by HCFA.

(e) *Resumption of payment—repeated instances of substandard care.* When HCFA denies payment for all Medi-

care residents for repeated instances of substandard quality of care, payment is resumed when—

(1) The facility achieved substantial compliance, as indicated by a revisit or written credible evidence acceptable to HCFA; and

(2) HCFA believes that the facility will remain in substantial compliance.

§ 488.422 State monitoring.

(a) A State monitor—

(1) Oversees the correction of deficiencies specified by HCFA or the State survey agency at the facility site and protects the facility's residents from harm;

(2) Is an employee or a contractor of the survey agency;

(3) Is identified by the State as an appropriate professional to monitor cited deficiencies;

(4) Is not an employee of the facility;

(5) Does not function as a consultant to the facility; and

(6) Does not have an immediate family member who is a resident of the facility to be monitored.

(b) A State monitor must be used when a survey agency has cited a facility with substandard quality of care deficiencies on the last 3 consecutive standard surveys.

(c) State monitoring is discontinued when—

(1) The facility has demonstrated that it is in substantial compliance with the requirements, and, if imposed

for repeated instances of substandard quality of care, will remain in compliance for a period of time specified by HCFA or the State; or

- (2) Termination procedures are completed.

[59 FR 56243, Nov. 10, 1994; 60 FR 50119, Sept. 28, 1995]

§ 488.424 Directed plan of correction.

HCFA, the State survey agency, or the temporary manager (with HCFA or State approval) may develop a plan of correction and HCFA, the State, or the temporary manager require a facility to take action within specified timeframes.

§ 488.425 Directed inservice training.

(a) *Required training.* HCFA or the State agency may require the staff of a facility to attend an inservice training program if—

- (1) The facility has a pattern of deficiencies that indicate noncompliance; and
- (2) Education is likely to correct the deficiencies.

(b) *Action following training.* After the staff has received inservice training, if the facility has not achieved substantial compliance, HCFA or the State may impose one or more other remedies specified in § 488.406.

(c) *Payment.* The facility pays for directed inservice training.

[59 FR 56243, Nov. 10, 1994; 60 FR 50119, Sept. 28, 1995]

§ 488.426 Transfer of residents, or closure of the facility and transfer of residents.

(a) *Transfer of residents, or closure of the facility and transfer of residents in an emergency.* In an emergency, the State has the authority to—

- (1) Transfer Medicaid and Medicare residents to another facility; or

(2) Close the facility and transfer the Medicaid and Medicare residents to another facility.

(b) *Required transfer when a facility's provider agreement is terminated.* When the State or HCFA terminates a facility's provider agreement, the State arranges for the safe and orderly transfer of all Medicare and Medicaid residents to another facility.

[59 FR 56243, Nov. 10, 1994; 60 FR 50119, Sept. 28, 1995]

§ 488.430 Civil money penalties: Basis for imposing penalty.

(a) HCFA or the State may impose a civil money penalty for the number of days a facility is not in substantial compliance with one or more participation requirements, regardless of whether or not the deficiencies constitute immediate jeopardy.

(b) HCFA or the State may impose a civil money penalty for the number of days of past noncompliance since the last standard survey, including the number of days of immediate jeopardy.

§ 488.432 Civil money penalties: When penalty is collected.

(a) *When facility requests a hearing.* (1) A facility must request a hearing on the determination of the noncompliance that is the basis for imposition of the civil money penalty within the time specified in one of the following sections:

- (i) Section 498.40 of this chapter for a
 - (A) SNF;
 - (B) Dually participating facility;
 - (C) State-operated NF; or
 - (D) Non-State operated NF against which HCFA is imposing remedies.
- (ii) Section 431.153 of this chapter for a non-State operated NF that is not subject to imposition of remedies by HCFA.

(2) If a facility requests a hearing within the time specified in paragraph (a)(1) of this section, HCFA or the State initiates collection of the penalty when there is a final administrative decision that upholds HCFA's or the State's determination of noncompliance after the facility achieves substantial compliance or is terminated.

(b) *When facility does not request a hearing.* If a facility does not request a hearing, in accordance with paragraph (a) of this section, HCFA or the State initiates collection of the penalty when the facility—

- (1) Achieves substantial compliance; or

(2) Is terminated.

(c) *When facility waives a hearing.* If a facility waives its right to a hearing in writing, as specified in § 488.436, HCFA or the State initiates collection of the penalty when the facility—

- (1) Achieves substantial compliance; or
- (2) Is terminated.
- (d) Accrual and computation of penalties for a facility that—
 - (1) Requests a hearing or does not request a hearing are specified in § 488.440;
 - (2) Waives its right to a hearing in writing, are specified in §§ 488.436(b) and 488.440.
- (e) The collection of civil money penalties is made as provided in § 488.442.

[59 FR 56243, Nov. 10, 1994; 60 FR 50119, Sept. 28, 1995]

§ 488.434 Civil money penalties: Notice of penalty.

(a) *HCFA notice of penalty.* (1) HCFA sends a written notice of the penalty to the facility for all facilities except non-State operated NFs when the State is imposing the penalty.

(2) *Content of notice.* The notice that HCFA sends includes—

- (i) The nature of the noncompliance;
- (ii) The statutory basis for the penalty;

- (iii) The amount of penalty per day of noncompliance;
- (iv) Any factors specified in § 488.438(f) that were considered when determining the amount of the penalty;
- (v) The date on which the penalty begins to accrue;
- (vi) When the penalty stops accruing;
- (vii) When the penalty is collected; and
- (viii) Instructions for responding to the notice, including a statement of the facility's right to a hearing, and the implication of waiving a hearing, as provided in § 488.436.

(b) *State notice of penalty.* (1) The State must notify the facility in accordance with State procedures for all non-State operated NFs when the State takes the action.

(2) The State's notice must—

- (i) Be in writing; and
- (ii) Include, at a minimum, the information specified in paragraph (a)(2) of this section.

[59 FR 56243, Nov. 10, 1994; 60 FR 50119, Sept. 28, 1995]

§ 488.436 Civil money penalties: Waiver of hearing, reduction of penalty amount.

- (a) *Waiver of a hearing.* The facility may waive the right to a hearing, in writing, within 60 days from the date of the notice imposing the civil money penalty.
- (b) *Reduction of penalty amount.* (1) If the facility waives its right to a hearing in accordance with the procedures specified in paragraph (a) of this section, HCFA or the State reduces the civil money penalty amount by 35 percent.
 - (2) If the facility does not waive its right to a hearing in accordance with the procedures specified in paragraph (a) of this section, the civil money penalty is not reduced by 35 percent.

[59 FR 56243, Nov. 10, 1994; 62 FR 44221, Aug. 20, 1997]

§ 488.438 Civil money penalties: Amount of penalty.

- (a) *Amount of penalty.* The penalties are within the following ranges, set at \$50 increments:
 - (1) *Upper range—\$3,050-\$10,000.* Penalties in the range of \$3,050-\$10,000 per day are imposed for deficiencies constituting immediate jeopardy, and as specified in paragraph (d)(2) of this section.
 - (2) *Lower range—\$50-\$3,000.* Penalties in the range of \$50-\$3,000 per day are imposed for deficiencies that do not constitute immediate jeopardy, but either caused actual harm, or caused no actual harm, but have the potential for more than minimal harm.

(b) *Basis for penalty amount.* The amount of penalty is based on HCFA's or the State's assessment of factors listed in paragraph (f) of this section.

(c) *Decreased penalty amounts.* Except as specified in paragraph (d)(2) of this section, if immediate jeopardy is removed, but the noncompliance continues, HCFA or the State will shift the penalty amount to the lower range.

(d) *Increased penalty amounts.* (1) Before the hearing, HCFA or the State may propose to increase the penalty amount for facility noncompliance which, after imposition of a lower level penalty amount, becomes sufficiently serious to pose immediate jeopardy.

(2) HCFA does and the State must increase the penalty amount for any repeated deficiencies for which a lower level penalty amount was previously imposed, regardless of whether the increased penalty amount would exceed the range otherwise reserved for non-immediate jeopardy deficiencies.

(3) Repeated deficiencies are deficiencies in the same regulatory grouping of requirements found at the last survey, subsequently corrected, and found again at the next survey.

(e) *Review of the penalty.* When an administrative law judge or State hearing officer (or higher administrative review authority) finds that the basis for imposing a civil money penalty exists, as specified in § 488.430, the administrative law judge or State hearing officer (or higher administrative review authority) may not—

(1) Set a penalty of zero or reduce a penalty to zero;

(2) Review the exercise of discretion by HCFA or the State to impose a civil money penalty; and

(3) Consider any factors in reviewing the amount of the penalty other than those specified in paragraph (f) of this section.

(f) *Factors affecting the amount of penalty.* In determining the amount of penalty, HCFA does or the State must take into account the following factors:

(1) The facility's history of noncompliance, including repeated deficiencies.

(2) The facility's financial condition.

(3) The factors specified in § 488.404.

(4) *The facility's degree of culpability.* Culpability for purposes of this paragraph includes, but is not limited to, neglect, indifference, or disregard for resident care, comfort or safety. The absence of culpability is not a mitigating circumstance in reducing the amount of the penalty.

§ 488.440 Civil money penalties: Effective date and duration of penalty.

(a) *When penalty begins to accrue.* The civil money penalty may start accruing as early as the date that the facility was first out of compliance, as determined by HCFA or the State.

(b) *Duration of penalty.* The civil money penalty is computed and collectible, as specified in §§ 488.432 and 488.442, for the number of days of noncompliance until the date the facility achieves substantial compliance, or, if applicable, the date of termination when—

(1) HCFA's or the State's decision of noncompliance is upheld after a final administrative decision;

(2) The facility waives its right to a hearing in accordance with § 488.436; or

(3) The time for requesting a hearing has expired and HCFA or the State has not received a hearing request from the facility.

(c) The entire accrued penalty is due and collectible, as specified in the notice sent to the provider under paragraphs (d) and (e) of this section.

(d) When a facility achieves substantial compliance, HCFA does or the State must send a separate notice to the facility containing—

(1) The amount of penalty per day;

(2) The number of days involved;

(3) The total amount due;

(4) The due date of the penalty; and

(5) The rate of interest assessed on the unpaid balance beginning on the due date, as provided in § 488.442.

(e) In the case of a terminated facility, HCFA does or the State must send this penalty information after the—

(1) Final administrative decision is made;

(2) Facility has waived its right to a hearing in accordance with § 488.436; or

(3) Time for requesting a hearing has expired and HCFA or the state has not received a hearing request from the facility.

(f) *Accrual of penalties when there is no immediate jeopardy.* (1) In the case of noncompliance that does not pose immediate jeopardy, the daily accrual of civil money penalties is imposed for the days of noncompliance prior to the notice specified in § 488.434 and an additional period of no longer than 6 months following the last day of the survey.

(2) After the period specified in paragraph (f)(1) of this section, if the facility has not achieved substantial compliance, HCFA terminates the provider agreement and the State may terminate the provider agreement.

(g) *Accrual of penalties when there is immediate jeopardy.* (1) When a facility has deficiencies that pose immediate jeopardy, HCFA does or the State must terminate the provider agreement within 23 calendar days after the last day of the survey if the immediate jeopardy remains.

(2) The accrual of the civil money penalty stops on the day the provider agreement is terminated.

(h) *Documenting substantial compliance.* (1) If an on-site revisit is necessary to confirm substantial compliance and the provider can supply documentation acceptable to HCFA or the State agency that substantial compliance was achieved on a date preceding the revisit, penalties only accrue until that date of correction for which there is written credible evidence.

(2) If an on-site revisit is not necessary to confirm substantial compliance, penalties only accrue until the date of

correction for which HCFA or the State receives and accepts written credible evidence.

§ 488.442 Civil money penalties: Due date for payment of penalty.

(a) *When payments are due—*(1) *After a final administrative decision.* A civil money penalty payment is due 15 days after a final administrative decision is made when—

(i) The facility achieves substantial compliance before the final administrative decision; or

(ii) The effective date of termination occurs before the final administrative decision.

(2) *When no hearing was requested.* A civil money penalty payment is due 15 days after the time period for requesting a hearing has expired and a hearing request was not received when—

(i) The facility achieved substantial compliance before the hearing request was due; or

(ii) The effective date of termination occurs before the hearing request was due.

(3) *After a request to waive a hearing.* A civil money penalty payment is due 15 days after receipt of the written request to waive a hearing when—

(i) The facility achieved substantial compliance before HCFA or the State received the written waiver of hearing; or

(ii) The effective date of termination occurs before HCFA or the State received the written waiver of hearing.

(4) *After substantial compliance is achieved.* A civil money penalty payment is due 15 days after substantial compliance is achieved when—

(i) The final administrative decision is made before the facility came into substantial compliance;

(ii) The facility did not file a timely hearing request before it came into substantial compliance; or

(iii) The facility waived its right to a hearing before it came into substantial compliance;

(5) *After the effective date of termination.* A civil money penalty payment is due 15 days after the effective date of termination, if before the effective date of termination—

(i) The final administrative decision was made;

(ii) The time for requesting a hearing has expired and the facility did not request a hearing; or

(iii) The facility waived its right to a hearing.

(6) In the cases specified in paragraph (a)(4) of this section, the period of noncompliance may not extend beyond 6 months from the last day of the survey.

(b) *Deduction of penalty from amount owed.* The amount of the penalty, when determined, may be deducted from any sum then or later owing by HCFA or the State to the facility.

(c) *Interest—*(1) *Assessment.* Interest is assessed on the unpaid balance of the penalty, beginning on the due date.

(2) *Medicare interest.* Medicare rate of interest is the higher of—

(i) The rate fixed by the Secretary of the Treasury after taking into consideration private consumer rates of interest prevailing on the date of the notice of the penalty amount due (published quarterly in the Federal Register by HHS under 45 CFR 30.13(a)); or

(ii) The current value of funds (published annually in the Federal Register by the Secretary of the Treasury, subject to quarterly revisions).

(3) *Medicaid interest.* The interest rate for Medicaid is determined by the State.

(d) *Penalties collected by HCFA.* Civil money penalties and corresponding interest collected by HCFA from—

(1) Medicare-participating facilities are deposited as miscellaneous receipts of the United States Treasury; and

(2) Medicaid-participating facilities are returned to the State.

(e) *Collection from dually participating facilities.* Civil money penalties collected from dually participating facilities are deposited as miscellaneous receipts of the United States Treasury and returned to the State in proportion commensurate with the relative proportions of Medicare and Medicaid beds at the facility actually in use by residents covered by the respective programs on the date the civil money penalty begins to accrue.

(f) *Penalties collected by the State.* Civil money penalties collected by the State must be applied to the protection of the health or property of residents of facilities that the State or HCFA finds noncompliant, such as—

(1) Payment for the cost of relocating residents to other facilities;

(2) State costs related to the operation of a facility pending correction of deficiencies or closure; and

(3) Reimbursement of residents for personal funds or property lost at a facility as a result of actions by the facility or by individuals used by the facility to provide services to residents.

[59 FR 56243, Nov. 10, 1994; 60 FR 50119, Sept. 28, 1995]

§ 488.444 Civil money penalties: Settlement of penalties.

(a) HCFA has authority to settle cases at any time prior to a final administrative decision for Medicare-only SNFs, State-operated facilities, or other facilities for which HCFA's enforcement action prevails, in accordance with § 488.330.

(b) The State has the authority to settle cases at any time prior to the evidentiary hearing decision for all cases in which the State's enforcement action prevails.

§ 488.450 Continuation of payments to a facility with deficiencies.

(a) *Criteria.* (1) HCFA may continue payments to a facility not in substantial compliance for the periods specified in paragraph (c) of this section if the following criteria are met:

(i) The State survey agency finds that it is more appropriate to impose alternative remedies than to terminate the facility;

(ii) The State has submitted a plan and timetable for corrective action approved by HCFA; and

(iii) The facility, in the case of a Medicare SNF, or the State, in the case of a Medicaid NF, agrees to repay the Federal government payments received under this provision if corrective action is not taken in accordance with the approved plan and timetable for corrective action.

(2) HCFA or the State may terminate the SNF or NF agreement before the end of the correction period if the criteria in paragraph (a)(1) of this section are not met.

(b) *Cessation of payments.* If termination is not sought, either by itself or along with another remedy or remedies, or any of the criteria set forth in paragraph (a)(1) of this section are not met or agreed to by either the facility or the State, the facility or State will receive no Medicare or Federal Medicaid payments, as applicable, from the last day of the survey.

(c) *Period of continued payments.* If the conditions in paragraph (a)(1) of this section are met, HCFA may continue payments to a Medicare facility or to the State for a Medicaid facility with noncompliance that does not constitute immediate jeopardy for up to 6 months from the last day of the survey.

(d) *Failure to achieve substantial compliance.* If the facility does not achieve substantial compliance by the end of the period specified in paragraph (c) of this section,

(1) HCFA will—

(i) Terminate the provider agreement of the Medicare SNF in accordance with § 488.456; or

(ii) Discontinue Federal funding to the SNF for Medicare; and

(iii) Discontinue FFP to the State for the Medicaid NF.

(2) The State may terminate the provider agreement for the NF.

[59 FR 56243, Nov. 10, 1994; 60 FR 50119, Sept. 28, 1995]

§ 488.452 State and Federal disagreements involving findings not in agreement in non-State operated NFs and dually participating facilities when there is no immediate jeopardy.

The following rules apply when HCFA and the State disagree over findings of noncompliance or application of remedies in a non-State operated NF or dually participating facility:

(a) *Disagreement over whether facility has met requirements.* (1) The State's finding of noncompliance takes precedence when—

(i) HCFA finds that a NF or a dually participating facility is in substantial compliance with the participation requirements; and

(ii) The State finds that a NF or dually participating facility has not achieved substantial compliance.

(2) HCFA's findings of noncompliance take precedence when—

(i) HCFA finds that a NF or a dually participating facility has not achieved substantial compliance; and

(ii) The State finds that a NF or a dually participating facility is in substantial compliance with the participation requirements.

(3) When HCFA's survey findings take precedence, HCFA may—

(i) Impose any of the alternative remedies specified in § 488.406;

(ii) Terminate the provider agreement subject to the applicable conditions of § 488.450; and

(iii) Stop FFP to the State for a NF.

(b) *Disagreement over decision to terminate.*

(1) HCFA's decision to terminate the participation of a facility takes precedence when—

(i) Both HCFA and the State find that the facility has not achieved substantial compliance; and

(ii) HCFA, but not the State, finds that the facility's participation should be terminated. HCFA will permit continuation of payment during the period prior to the effective date of termination not to exceed 6 months, if the applicable conditions of § 488.450 are met.

(2) The State's decision to terminate a facility's participation and the procedures for appealing such termination, as specified in § 431.153(c) of this chapter, takes precedence when—

(i) The State, but not HCFA, finds that a NF's participation should be terminated; and

(ii) The State's effective date for the termination of the NF's provider agreement is no later than 6 months after the last day of survey.

(c) *Disagreement over timing of termination of facility.* The State's timing of termination takes precedence if it does not occur later than 6 months after the last day of the survey when both HCFA and the State find that—

- (1) A facility is not in substantial compliance; and
- (2) The facility's participation should be terminated.

(d) *Disagreement over remedies.* (1) When HCFA or the State, but not both, establishes one or more remedies, in addition to or as an alternative to termination, the additional or alternative remedies will also apply when—

(i) Both HCFA and the State find that a facility has not achieved substantial compliance; and

(ii) Both HCFA and the State find that no immediate jeopardy exists.

(2) *Overlap of remedies.* When HCFA and the State establish one or more remedies, in addition to or as an alternative to termination, only the HCFA remedies apply when both HCFA and the State find that a facility has not achieved substantial compliance.

(e) Regardless of whether HCFA's or the State's decision controls, only one noncompliance and enforcement decision is applied to the Medicaid agreement, and for a dually participating facility, that same decision will apply to the Medicare agreement.

§ 488.454 Duration of remedies.

(a) Except as specified in paragraph (b) of this section, alternative remedies continue until—

(1) The facility has achieved substantial compliance, as determined by HCFA or the State based upon a revisit or after an examination of credible written evidence that it can verify without an on-site visit; or

(2) HCFA or the State terminates the provider agreement.

(b) In the cases of State monitoring and denial of payment imposed for repeated substandard quality of care, remedies continue until—

(1) HCFA or the State determines that the facility has achieved substantial compliance and is capable of remaining in substantial compliance; or

(2) HCFA or the State terminates the provider agreement.

(c) In the case of temporary management, the remedy continues until—

(1) HCFA or the State determines that the facility has achieved substantial compliance and is capable of remaining in substantial compliance;

(2) HCFA or the State terminates the provider agreement; or

(3) The facility which has not achieved substantial compliance reassumes management control. In this case, HCFA

or the State initiates termination of the provider agreement and may impose additional remedies.

(d) If the facility can supply documentation acceptable to HCFA or the State survey agency that it was in substantial compliance, and was capable of remaining in substantial compliance, if necessary, on a date preceding that of the revisit, the remedies terminate on the date that HCFA or the State can verify as the date that substantial compliance was achieved and the facility demonstrated that it could maintain substantial compliance, if necessary.

[59 FR 56243, Nov. 10, 1994; 60 FR 50119, Sept. 28, 1995]

§ 488.456 Termination of provider agreement.

(a) *Effect of termination.* Termination of the provider agreement ends—

- (1) Payment to the facility; and
- (2) Any alternative remedy.

(b) *Basis for termination.* (1) HCFA and the State may terminate a facility's provider agreement if a facility—

(i) Is not in substantial compliance with the requirements of participation, regardless of whether or not immediate jeopardy is present; or

(ii) Fails to submit an acceptable plan of correction within the time-frame specified by HCFA or the State.

(2) HCFA and the State terminate a facility's provider agreement if a facility—

(i) Fails to relinquish control to the temporary manager, if that remedy is imposed by HCFA or the State; or

(ii) Does not meet the eligibility criteria for continuation of payment as set forth in § 488.412(a)(1).

(c) *Notice of termination.* Before terminating a provider agreement, HCFA does and the State must notify the facility and the public—

(1) At least 2 calendar days before the effective date of termination for a facility with immediate jeopardy deficiencies; and

(2) At least 15 calendar days before the effective date of termination for a facility with non-immediate jeopardy deficiencies that constitute noncompliance.

(d) *Procedures for termination.* (1) HCFA terminates the provider agreement in accordance with procedures set forth in § 489.53 of this chapter; and

(2) The State must terminate the provider agreement of a NF in accordance with procedures specified in parts 431 and 442 of this chapter.

5. Section 498 of Title 42, Code of Federal Regulations, provides in relevant part:

§ 498.1 Statutory basis.

(a) Section 1866(h) of the Act provides for a hearing and for judicial review of the hearing for any institution or agency dissatisfied with a determination that it is not a provider, or with any determination described in section 1866(b)(2) of the Act.

(b) Section 1866(b)(2) of the Act lists determinations that serve as a basis for termination of a provider agreement.

(c) Sections 1128(a) and (b) of the Act provide for exclusion of certain individuals or entities because of conviction of crimes related to their participation in Medicare and section 1128(f) provides for hearing and judicial review for exclusions.

(d) Section 1156 of the Act establishes certain obligations for practitioners and providers of health care services, and provides sanctions and penalties for those that fail to meet those obligations.

* * * *

(i) *Section 1819(h) of the Act—*

(1) Provides that, for SNFs found to be out of compliance with the requirements for participation, specified remedies may be imposed instead of, or in addition to, termination of the facility's Medicare provider agreement; and

(2) Makes certain provisions of section 1128A of the Act applicable to civil money penalties imposed on SNFs.

* * * *

§ 498.3 Scope and applicability.

(a) *Scope.* This part sets forth procedures for reviewing initial determinations that HCFA makes with respect to the matters specified in paragraph (b) of this section, and that the OIG makes with respect to the matters specified in paragraph (c) of this section. It also specifies, in paragraph (d) of this section, administrative actions that are not subject to appeal under this part.

(b) *Initial determinations by HCFA.* HCFA makes initial determinations with respect to the following matters:

(1) Whether a prospective provider qualifies as a provider.

(2) Whether an institution is a hospital qualified to elect to claim payment for all emergency hospital services furnished in a calendar year.

(3) Whether an institution continues to remain in compliance with the qualifications for claiming reimbursement for all emergency services furnished in a calendar year.

(4) Whether a prospective supplier meets the conditions for coverage of its services as those conditions are set forth elsewhere in this chapter.

(5) Whether the services of a supplier continue to meet the conditions for coverage.

(6) Whether a physical therapist in independent practice or a chiropractor meets the requirements for coverage of his

or her services as set forth in subpart D of part 486 of this chapter and § 410.22 of this chapter, respectively.

(7) The termination of a provider agreement in accordance with § 489.53 of this chapter, or the termination of a rural health clinic agreement in accordance with § 405.2404 of this chapter, or the termination of a Federally qualified health center agreement in accordance with § 405.2436 of this chapter.

(8) HCFA's cancellation, under section 1910(b) of the Act, of an ICF/MR's approval to participate in Medicaid.

(9) Whether, for purposes of rate setting and reimbursement, an ESRD treatment facility is considered to be hospital-based or independent.

(10) Whether to deny payment under § 409.19 or § 409.64 of this chapter, pertaining to cardiac pacemakers and the pacemaker registry.

(11) Whether a hospital, skilled nursing facility, home health agency, or hospice program meets or continues to meet the advance directives requirements specified in subpart I of part 489 of this chapter.

(12) With respect to an SNF or NF, a finding of noncompliance that results in the imposition of a remedy specified in § 488.406 of this chapter, except the State monitoring remedy, and the loss of the approval for a nurse-aide training program.

(13) The level of noncompliance found by HCFA in an SNF or NF but only if a successful challenge on this issue would affect the range of civil money penalty amounts that HCFA could collect. (The scope of review during a hearing

on imposition of a civil money penalty is set forth in § 488.438(e) of this chapter.)

(14) The effective date of a Medicare provider agreement or supplier approval.

(c) *Initial determinations by the OIG.* The OIG makes initial determinations with respect to the following matters:

(1) The termination of a provider agreement in accordance with Part 1001, Subpart C of this title.

(2) The suspension, or exclusion from coverage and the denial of reimbursement for services furnished by a provider, practitioner, or supplier, because of fraud or abuse, or conviction of crimes related to participation in the program, in accordance with Part 1001, Subpart B of this title.

(3) The imposition of sanctions in accordance with Part 1004 of this title.

(d) *Administrative actions that are not initial determinations.* Administrative actions that are not initial determination (and therefore not subject to appeal under this part) include but are not limited to the following:

(1) The finding that a provider or supplier determined to be in compliance with the conditions or requirements for participation or for coverage has deficiencies.

(2) The finding that a prospective provider does not meet the conditions of participation set forth elsewhere in this chapter, if the prospective provider is, nevertheless, approved for participation in Medicare on the basis of special access certification, as provided in subpart B of part 488 of this chapter.

(3) The refusal to enter into a provider agreement because the prospective provider is unable to give satisfactory assurance of compliance with the requirements of title XVIII of the Act.

(4) The finding that an entity that had its provider agreement terminated may not file another agreement because the reasons for terminating the previous agreement have not been removed or there is insufficient assurance that the reasons for the exclusion will not recur.

(5) The determination not to reinstate a suspended or excluded practitioner, provider, or supplier because the reason for the suspension or exclusion has not been removed, or there is insufficient assurance that the reason will not recur.

(6) The finding that the services of a laboratory are covered as hospital services or as physician's services, rather than as services of an independent laboratory, because the laboratory is not independent of the hospital or of the physician's office.

(7) The refusal to accept for filing an election to claim payment for all emergency hospital services furnished in a calendar year because the institution—

(i) Had previously charged an individual or other person for services furnished during that calendar year;

(ii) Submitted the election after the close of that calendar year; or

(iii) Had previously been notified of its failure to continue to comply.

(8) The finding that the reason for the revocation of a supplier's right to accept assignment has not been removed or there is insufficient assurance that the reason will not recur.

(9) The finding that a hospital accredited by the Joint Commission on Accreditation of Hospitals or the American Osteopathic Association is not in compliance with a condition of participation, and a finding that that hospital is no longer deemed to meet the conditions of participation.

(10) With respect to an SNF or NF-

(i) The finding that the SNF's or NF's deficiencies pose immediate jeopardy to the health or safety of its residents;

(ii) Except as provided in paragraph (b)(13) of this section, a determination by HCFA as to the facility's level of noncompliance; and

(iii) The imposition of State monitoring or the loss of the approval for a nurse-aide training program.

(11) The choice of alternative sanction or remedy to be imposed on a provider or supplier.

(12) The determination that the accreditation requirements of a national accreditation organization do not provide (or do not continue to provide) reasonable assurance that the entities accredited by the accreditation organization meet the applicable long-term care requirements, conditions for coverage, conditions of certification, conditions of participation, or CLIA condition level requirements.

(13) The determination that requirements imposed on a State's laboratories under the laws of that State do not provide (or do not continue to provide) reasonable assurance

that laboratories licensed or approved by the State meet applicable CLIA requirements.

(14) The choice of alternative sanction or remedy to be imposed on a provider or supplier.

(15) A decision by the State survey agency as to when to conduct an initial survey of a prospective provider or supplier.

(e) *Exclusion of civil rights issues.* The procedures in this subpart do not apply to the adjudication of issues relating to a provider's compliance with civil rights requirements that are set forth in Part 489 of this chapter. Those issues are handled through the Department's Office of Civil Rights.

APR 29 1999

OFFICE OF THE CLERK

In The
Supreme Court of the United States

DONNA E. SHALALA,
SECRETARY OF HEALTH AND HUMAN SERVICES, ET AL.,
PETITIONERS,

v.

ILLINOIS COUNCIL ON LONG TERM CARE, INC.

**On Petition For A Writ of Certiorari
To The United States Court of Appeals
For the Seventh Circuit**

BRIEF FOR THE RESPONDENT

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QUESTION PRESENTED

Whether 42 U.S.C. § 405(h), incorporated into the Medicare Act by 42 U.S.C. § 1395ii, precludes jurisdiction under 28 U.S.C. §§ 1331 and 1346 over an action asserting constitutional and statutory challenges to Medicare regulations where the contentions alleged cannot be considered in the administrative review process and are unrelated to an individual claim.

(i)

RULE 29.1 STATEMENT

Respondent Illinois Council on Long Term Care, Inc., an Illinois not-for-profit corporation, in compliance with Supreme Court Rule 29.1, states that it has no affiliated corporations, either as a parent, subsidiary or otherwise.

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No. 98-1109

In The
SUPREME COURT OF THE UNITED STATES

DONNA E. SHALALA,
SECRETARY OF HEALTH AND HUMAN SERVICES,
ET AL.,
PETITIONERS,

v.
ILLINOIS COUNCIL ON LONG TERM CARE, INC.

On Writ of Certiorari To The
United States Court of Appeals
For the Seventh Circuit

BRIEF FOR THE RESPONDENT

**STATUTORY AND REGULATORY PROVISIONS
INVOLVED**

Pertinent statutory and regulatory provisions are set forth in the appendix to the Secretary's brief and in the appendix hereto.

STATEMENT OF THE CASE

The Illinois Council on Long Term Care, Inc.

The Illinois Council on Long Term Care, Inc. (the Council), is an Illinois not-for-profit trade association comprised of more than 180 nursing homes. J.A. 19. The Council is chartered to provide continuing education programs to nursing home professionals, problem resolution and advocacy with regulatory agencies and to develop public policy through membership on state and local advisory boards. It maintains a prominent role in representing the long term care community, and serves as a liaison between state, municipal and federal agencies. R. 24, ex. H & I. Its goal is to "foster and maintain a high standard of service to the residents and to the

public in the operation of long term care facilities managed by its members." R.24, ex. I. The Council's Board of Directors has authorized it to pursue this litigation and has deemed the purposes of this litigation as being consistent with the Council's mission. *Id.*

The Council's Complaint

In 1987, Congress amended the Social Security Act with the Omnibus Budget Reconciliation Act, Pub. L. No. 100-203, §§ 4201-4218, 101 Stat. 1330 (1987) (OBRA 87). See Pet. App. 14a. The amendments called for stricter guidelines and more severe penalties for providers not satisfying minimum health and safety standards. 42 U.S.C. § 1395i-3. The Secretary published regulations implementing the minimum health and safety standards on October 1, 1990. 42 C.F.R. § 483, Subparts E and F. The Council does not challenge or seek to overturn the health and safety standards. J.A. 17.

OBRA 87 directed the Secretary to develop enforcement regulations for nursing facilities participating in Medicare and Medicaid. 42 U.S.C. § 1395i-3(g)(1)(A). Implementing enforcement regulations for the 1987 amendments, however, did not take effect until July 1, 1995 (hereafter 1995 Regulations). Pet. App. 1a. Before the 1995 Regulations went into effect, 6% of nursing homes in Illinois were found to be out of compliance with the requirements to participate in Medicare and Medicaid. Pet. App. 14a. After the 1995 regulations went into effect, nearly 70% of nursing homes in Illinois were found deficient. Pet. App. 2a, 14a.

The Council filed suit in federal district court challenging the 1995 Regulations and seeking declaratory and injunctive relief. The Council asserts constitutional and statutory challenges to the 1995 Regulations and to a State Operations Manual (hereinafter SOM) used by government inspectors of nursing homes. J.A. 17, 49-53. The Council's Amended Complaint seeks declaratory and injunctive relief regarding the following statutory and constitutional claims:

- a) The Secretary's 1995 enforcement regulations are void for vagueness;
- b) The 1995 Regulations and SOM violate the APA because they are substantive rules that deviate from and exceed the legislative mandate of federal statutes;
- c) The administrative review system contained in the 1995 regulations is so restrictive that it violates procedural due process; and
- d) The Secretary has failed to adequately implement programs to measure and reduce inconsistency in survey results in violation of the Social Security Act.¹

Statutory and Regulatory Framework

The Declaratory Judgment Act

From the founding of the nation, the federal courts have been viewed as the safeguard against unconstitutional laws passed by Congress. The courts also have been viewed as a check on the executive branch if it exceeded its authority in implementing the law. The Constitution, as signed in 1787, gave this Court (and other courts as Congress may establish) jurisdiction over cases arising under the Constitution and federal law, and jurisdiction over cases where the United States is a party.²

¹ For additional information on the merits of the Council's claims, see the Joint Appendix which contains the Council's Amended Complaint and relevant portions of the SOM. See also Pet. Brief 8-13.

² Article III of the U.S. Constitution declares in pertinent part:
Section 1: The judicial Power of the United States, shall be vested in one Supreme Court, and in such inferior Courts as the Congress may from time to time ordain and establish.
Section 2: Clause 1: The judicial Power shall extend to all Cases, in Law and Equity, arising under the Constitution, the Laws of the United States, and . . . to Controversies to which the United States shall be a Party . . .

The Council's jurisdictional bases in this case, 28 U.S.C. § 1331 (federal question), and 28 U.S.C. § 1346 (United States as a defendant),³ derive ultimately from Article III of the Constitution. This Court and the lower federal courts have a long history of declaring statutes and regulations unconstitutional in appropriate cases.

In 1934, Congress enacted a federal declaratory judgment statute. See 28 U.S.C. § 2201.⁴ During the enactment process, Congress recognized the declaratory judgment's utility in testing the validity of statutes. The Senate Report states that "now it is often necessary, in the absence of the declaratory judgment procedure, to violate or purport to violate a statute in order to obtain a judicial determination of its meaning or validity." S. Rep. No. 1005, 73rd Cong., 2d. Sess., at 2-3 (1934). The Report continues: "In jurisdictions having the declaratory judgment procedure, it is not necessary to bring about such social and economic waste and destruction in order to obtain a determination of one's rights." *Id.* at 3. Since its enactment in 1934, the Declaratory Judgment Act frequently has been used to challenge the validity of statutes or regulations in section 1331 cases.

³ 28 U.S.C. § 1331 provides: "The district courts shall have original jurisdiction of all civil actions arising under the Constitution, laws, or treaties of the United States."

28 U.S.C. § 1346 provides in pertinent part:

(a) The district courts shall have original jurisdiction, concurrent with the United States Court of Federal Claims, of . . . (2) Any other civil action or claim against the United States, not exceeding \$10,000 in amount, founded either upon the Constitution, or any Act of Congress, or any regulation of an executive department . . .

⁴ The current federal declaratory judgment statute reads in pertinent part:

In a case of actual controversy within its jurisdiction, . . . any court of the United States, upon the filing of an appropriate pleading, may declare the rights and other legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought. Any such declaration shall have the force and effect of a final judgment or decree and shall be reviewable as such.

28 U.S.C. § 2201 (original version at 28 U.S.C. § 400 (1934)).

The Social Security Act

Congress passed in 1935 the Social Security Act. See ch. 531, 49 Stat. 620. Its purpose is to provide benefits to protect against some of the burdens of modern existence through payments in the form of annuities to the elderly and compensation to workers during periods of unemployment. *E.g., United States v. Silk*, 331 U.S. 704, 710 & n.5 (1947) (citing legislative history).

In 1939, Congress amended the Social Security Act by adding administrative and judicial review provisions for individuals applying for benefits. Those provisions appear (as amended) at 42 U.S.C. § 405(b), (g) and (h). See Social Security Act Amendments of 1939, ch. 666, 53 Stat. 1360. Section 405(h) reads, in its entirety:

The findings and decisions of the Commissioner of Social Security after a hearing shall be binding upon all individuals who were parties to such hearing. No findings of fact or decision of the Commissioner of Social Security shall be reviewed by any person, tribunal, or governmental agency except as herein provided. No action against the United States, the Commissioner of Social Security, or any officer or employee thereof shall be brought under section 1331 or 1346 of title 28, United States Code, *to recover on any claim arising under this title*.

42 U.S.C. § 405(h) (emphasis added). As the highlighted language demonstrates, section 405(h) on its face encompasses only actions "to recover on any claim arising under this title."

The Administrative Procedure Act

Seven years later, in 1946, Congress enacted the Federal Administrative Procedure Act (APA), ch. 324, 60 Stat. 237 (codified as amended at 5 U.S.C. §§ 551-559, 701-706). It was "a new, basic and comprehensive regulation of procedures in many agencies," *Wong Yang Sung v. McGrath*, 339 U.S. 33, 36 (1950), and it provided minimum standards of administrative procedure. Section 703 of the APA provides that in the absence

or inadequacy of a special statutory forum to challenge administrative action, a party can bring any form of legal challenge, including declaratory judgments and injunctions, in a court of competent jurisdiction:

The form of proceeding for judicial review is the special statutory review proceeding relevant to the subject matter in a court specified by statute or, in the absence or inadequacy thereof, any applicable form of legal action, including actions for declaratory judgments or writs of prohibitory or mandatory injunction or habeas corpus, in a court of competent jurisdiction....

5 U.S.C. § 703. The legislative history for the APA contains the following statement by the Senate Committee on the Judiciary:

Very rarely do statutes withhold judicial review. It has never been the policy of Congress to prevent the administration of its own statutes from being judicially confined to the scope of authority granted or to the objectives specified. Its policy could not be otherwise, for in such a case statutes would in effect be blank checks drawn to the credit of some administrative officer or board.

S. Rep. No. 752, 79th Cong., 1st Sess., at 26 (1945). Accord H.R. Rep. No. 1980, 79th Cong., 2d. Sess., at 41 (1946). The legislative history further establishes the "clear and convincing evidence" standard of proof to preclude judicial review when statutes are not specific in withholding review:

To preclude judicial review under this bill a statute, if not specific in withholding such review, must upon its face give clear and convincing evidence of an intent to withhold it. The mere failure to provide specially by statute for judicial review is certainly no evidence of intent to withhold review.

H.R. Rep. No. 1980, 79th Cong., 2d. Sess., at 41 (1946). The legislative history of section 703 of the APA also reveals that Congress intended that pre-enforcement declaratory judgment actions would continue to be used to test the validity of administrative action:

Declaratory judgment procedure, for example, may be operative before statutory forms of review are available and may be utilized to determine the validity or application of any agency action. By such an action the court must determine the validity or application of a rule or order, render a judicial declaration of rights, and so bind an agency upon the case stated and in the absence of a reversal.

Id. at 42 (1946). Accord S. Rep. No. 752, 79th Cong., 1st Sess., at 26 (1945).

The Medicare Act

In 1965, Congress amended the Social Security Act, adding Title XVIII -- the Medicare Act -- to provide medical insurance for the elderly and disabled. Pub. L. No. 89-97, 79 Stat. 291 (codified as amended at 42 U.S.C. § 1395 *et seq.*). The Medicare Act established an expansive new federal program with complex provisions, including requirements for program participation and amounts of benefits for many medical services. Regarding appeal rights and judicial review of administrative determinations, Medicare simply incorporated by reference the hearing and judicial review provisions of sections 405(b), (g) and (h) from the Social Security Act. See 42 U.S.C. §§ 1395ff(a) and (b) (if an individual participating in Part A of Medicare Program is not satisfied with entitlement or amount of benefits, that individual is entitled to hearing and judicial review as provided by sections 405(b) and (g)); 42 U.S.C. § 1395cc(h) (if provider is dissatisfied concerning compliance determinations, certification or termination of provider agreement, administrative appeal and judicial review is provided through sections 405(b) and (g)); and 42 U.S.C. § 1395ii (incorporating 42 U.S.C. § 405(h) into Medicare Act).⁵

⁵ In 1965, Congress also amended the Social Security Act with Title XIX -- the Medicaid Act. Congress did not, however, incorporate into the Medicaid Act sections 1395ii or 405(h). See Pet App. 7a. Amount determinations and claims for benefits under Medicaid are not determined by Secretary, but by the state Medicaid agency.

On their face, these provisions pertain only to individual claims regarding benefits or provider status.

The District Court Decision

In its Amended Complaint, the Council asserted separate counts on behalf of its 75 members who participate solely in Medicaid, and separate counts for the remainder who participate in both Medicare and Medicaid. Pet. 7, n.5. The district court dismissed all counts of the complaint for lack of subject matter jurisdiction. Pet. App. 3a.⁶

The district court held that 42 U.S.C. § 405(h) deprived it of jurisdiction because the Council's claims "arise under" the Medicare act, relying on *Heckler v. Ringer*, 466 U.S. 602 (1984). Pet. App. 16a. The district court also construed the amended complaint as a "claim for benefits," Pet. App. 17a, even though the complaint was for "injunctive and declaratory relief." Pet. App. 13a. The district court also declined to follow *Bowen v. Michigan Academy of Family Physicians*, 476 U.S. 667 (1986). It concluded that because Congress amended the Medicare Act to provide appeal rights under Part B, "the concern noted in *Michigan Academy*, no longer exists because all participants now have an avenue of judicial review within HHS." Pet. App. 18a.

The Seventh Circuit Decision

The Seventh Circuit reversed, holding that the Council's lawsuit is not an action "to recover" on a claim arising under Medicare within the meaning of section 405(h), and therefore, is not barred. Pet. App. 6a. The court followed the more recent precedent of *Michigan Academy* instead of *Heckler v. Ringer*. The court acknowledged that "*Ringer and Salfi* [422 U.S. 749 (1975)] treat [405(h)'s] language as channeling all claims to

⁶ The Seventh Circuit reversed the district court's dismissal of the Medicaid counts. Pet. App. 7a-9a. The Secretary does not challenge that part of the Seventh Circuit's decision. See Pet. 7, n.5; see also Pet. Brief 15-16, n.14. Accordingly, the Seventh Circuit's conclusion that a Medicaid provider is not prevented from bringing a pre-enforcement challenge under section 1331 to a Medicaid regulation is not before the Court. See Pet. App. 9a.

benefits through the administrative forum, no matter what legal theory underlies the claim." Pet. App. 4a (emphasis added). It recognized, however, that this Court more recently in *Michigan Academy*, 476 U.S. at 678-81, held "that § 1395ii (which incorporates 405(h)) does not foreclose Medicare providers' anticipatory challenge to implementing regulations." Pet. App. 4a. The Seventh Circuit also rejected the district court's conclusion that in *Michigan Academy* this Court carved out an "exception" to statutory exhaustion requirements. Writing for the panel, Judge Easterbrook explained that *Michigan Academy* does not say that a presumption of judicial review justifies an exception to exhaustion requirements. Pet. App. 6a. Rather, *Michigan Academy* says that section 1395ii, in light of its legislative history, pertains to individual amounts determinations. *Id.*

In addition, the Seventh Circuit rejected the Secretary's argument (and the conclusion of the district court) that "*Michigan Academy* ceased to have any precedential force a few months after it was issued." Pet. App. 4a. The Seventh Circuit explained that "[s]hortly after the Court decided *Michigan Academy*, Congress amended the Medicare Act to give providers an avenue of judicial review of amount determinations, 42 U.S.C. § 1395ff(b)(1), thus overturning the result of *United States v. Erika, Inc.*, 456 U.S. 201, 102 S. Ct. 1650, 72 L.Ed.2d 12 (1982)." Pet. App. 4a-5a. This amendment, however, did not cause *Michigan Academy*'s entire holding to lose its precedential force. *Id.* at 5a. The Seventh Circuit observed that, after the amendments, this Court "in 1991 reiterated its conclusion that § 1395ii does not affect regulatory challenges that are detached from any request for reimbursement." *Id.* at 5a (citing *McNary v. Haitian Refugee Center, Inc.*, 498 U.S. 479, 497-98 (1991)). The Seventh Circuit recognized that the 1986 amendments allowed additional review for "amount determinations" under Part B. The Seventh Circuit explained that "[n]ow that Congress has authorized review of amount determinations through § 1395ff(b)(1), that part of *Michigan Academy*'s rationale is gone—the invalidity of regulations would be a good reason for a reviewing court to

upset an *amount determination*." Pet. App. 5a (emphasis added). But the Seventh Circuit further explained that "[n]either this critical language from § 405(h) nor the history of § 1395ii changed in 1986. . . . The operative language is the same now as when *Michigan Academy* came down." Pet. App. 6a-7a.

The Seventh Circuit further concluded that the Council has standing as a trade association to bring its claims: "If some nursing homes may litigate on their own, they may litigate through their trade association; we don't see why the fact that other members of the Council have potential Medicare claims should cut off associational representation and compel independent litigation." Pet. App. 8a.⁷

The Seventh Circuit also reversed the district court's conclusion that jurisdiction did not exist under the Medicaid Act (which contains no provisions like sections 1395ii or 405(h)). Pet. App. 7a-8a. The Seventh Circuit recognized that general federal question jurisdiction under § 1331 exists and it

⁷ There is no dispute that the Council has standing. This Court has long recognized that "[e]ven in the absence of injury to itself, an association may have standing solely as the representative of its members." *Warth v. Seldin*, 422 U.S. 490, 511 (1975). Several of the cases relied upon by the Secretary and the Council were brought by associations suing on behalf of their members. See *Bowen v. Michigan Academy of Family Physicians*, 476 U.S. 667 (1986); *Abbott Laboratories v. Gardner*, 387 U.S. 136, 138 (1967); *McNary v. Haitian Refugee Center, Inc.*, 498 U.S. 479, 487 (1991). This Court's long-standing test regarding associational standing was articulated in *Hunt v. Washington Apple Advertising Comm'n*, 432 U.S. 333 (1977). That the Council satisfies the *Hunt* test has not been disputed by either court below. The Secretary's brief does not argue that the Council lacks standing. Therefore, standing is not an issue before this Court.

There also can be no argument that this case is mooted by the interim final rule promulgated by the Department of Health and Human Services on July 23, 1999. See Medicare and Medicaid Program; Appeal of the Loss of Nurse Aid Training Programs, 64 Fed. Reg. 39,934 (1999). This action by the Secretary remedies only a small subset of the Due Process violations complained of by the Council. The Council's APA claim remains unchanged. Moreover, "voluntary cessation of a challenged practice" does not deprive this Court of the power to hear this case. See *City of Mesquite v. Aladdin's Castle, Inc.*, 455 U.S. 283, 289 (1982).

supplies the avenue of judicial review. Pet. App. 7a.

The Seventh Circuit rejected "across the board" the Sixth Circuit's decision in *Michigan Association of Homes & Services for the Aging, Inc. v. Shalala*, 127 F.3d 496 (CA6 1997), *reh'g denied*, 1997 U.S. App. LEXIS 37154 (CA6 1997). Pet. App. 8a. The Sixth Circuit, in contrast with the Seventh Circuit decision below, concluded that: (1) so long as a plaintiff's standing and substantive bases for its claims arise under the Medicare Act, section 405(h) bars judicial review (following *Weinberger v. Salfi*, 422 U.S. 749 (1975) and *Heckler v. Ringer*, 466 U.S. 602, 622 (1984)); (2) *Michigan Academy* and *McNary* carve out an exception to 405(h) in cases of futility; (3) the "exception to exhaustion" of *Michigan Academy* did not apply, and that exhaustion was required; and (4) exhaustion is not futile because a nursing home could raise constitutional claims in a federal court after exhausting administrative remedies.⁸

The Seventh Circuit panel's decision was unanimous. On the Secretary's petition for rehearing, even though the decision created a split with the Sixth Circuit, the majority of active judges on the Seventh Circuit, including the three panel judges, voted against rehearing *en banc*. Pet. App. 22a-23a.

SUMMARY OF THE ARGUMENT

1. The plain language of sections 405(b), (g) and (h) of the Social Security Act demonstrates that Congress intended section 405(h) to preclude only *individual* claims for benefits for which there is an available administrative hearing under section 405(b), and which would result in a decision by the Secretary that could be reviewed meaningfully in an appeal to a

⁸ The Sixth Circuit also held that jurisdiction over the Association's claims pertaining to Medicaid was precluded, even though the Medicaid Act did not incorporate the jurisdictional bar of section 405(h). *Michigan Association*, 127 F.3d at 502-3. By not contesting the Seventh Circuit's conclusion that jurisdiction exists for Medicaid, the Secretary is tacitly conceding the Sixth Circuit's error in concluding that jurisdiction is barred for claims arising under Medicaid. Even though the Secretary does not contest Medicaid jurisdiction here, this Court should overrule the Sixth Circuit's Medicaid holding to resolve the circuit split on that point.

district court under section 405(g). When sections 405(b), (g) and (h) were incorporated by reference into the Medicare Act through sections 1395ff, 1395cc(h) and 1395ii, the meaning and purpose of those provisions did not change. The plain language of the Medicare provisions again reveals congressional intent to require exhaustion only of individual claims regarding benefits or provider status. The legislative history confirms this conclusion. Moreover, this Court held in *Bowen v. Michigan Academy of Family Physicians*, 476 U.S. 667, 680 (1986), that section 1395ii pertains to individual "amount determinations," and that other claims, such as challenges to the validity of regulations, are not barred. The Seventh Circuit below simply followed that holding of *Michigan Academy*.

2. The Secretary's statutory construction would deny meaningful review of statutory and constitutional challenges to the validity of the Secretary's regulations. A district court considering an administrative appeal under section 405(g) is limited to the administrative record and may only affirm, modify or reverse a decision of the Secretary. The Secretary concedes that statutory and constitutional challenges to regulations cannot be raised in the administrative review process. Consequently, there will be neither a decision nor an administrative record regarding such issues for a federal court to review on appeal, as this Court observed in *McNary v. Haitian Refugee Center Inc.*, 498 U.S. 479, 496-97 (1991). Moreover, the plain language of section 405(g) reveals that a reviewing district court considers only the validity of Secretary's regulations regarding an individual's burden of proof in an administrative hearing. Neither the language nor legislative history of section 405(g) suggests that Congress intended for federal courts to consider broad statutory and constitutional challenges under section 405(g).

3. Properly construed, sections 1395ii and 405(h) do not divest federal courts of plenary jurisdiction over the Council's case. The Council asserts constitutional and statutory challenges to specific regulations and enforcement practices. This Court has long embraced the view that statutory or constitutional

challenges to regulations are collateral to a substantive claim of entitlement, and that jurisdiction exists for such claims. Here, the Council is not asserting an individual claim. The Council is a trade association; it has no provider agreement. Because the Council has no access to the administrative review process, and its constitutional and statutory challenges could not be considered in an administrative appeal in any event, section 405(h) does not bar its lawsuit.

4. *Michigan Academy* and *McNary* compel affirmance of the Seventh Circuit's decision. In *Michigan Academy* this Court rejected many of the Secretary's arguments here. This Court held that challenges to regulations cannot be considered in the administrative review process, and that such claims are cognizable in courts of law. 476 U.S. at 680. This Court recognized that a challenge to the validity of a regulation is not a challenge to a "decision" after a "hearing" as those words appear in section 405(h). *Id.* at 674, n.8. The Secretary's argument that *Michigan Academy* lost precedential value after the 1986 amendments lacks merit because this Court has continued to rely on *Michigan Academy* after 1986. As the Seventh Circuit concluded, the amendments did not change the operative language of sections 405(h) and 1395ii, nor the viability of *Michigan Academy*'s holding. *McNary* likewise supports affirmance. In *McNary*, this Court held that the words "a determination" describe "a single act rather than a group of decisions or a practice or procedure employed in making decisions." 498 U.S. at 492. This Court further held that federal court jurisdiction is available when a claimant "would not as a practical matter be able to obtain meaningful judicial review" after exhausting administrative remedies. *Id.* at 496.

5. The Secretary's policy arguments are irrelevant in this statutory construction case, and in any event, are meritless. The traditional justifications for exhaustion do not apply here. No agency expertise exists for the Council's challenges; nor would consideration of the Council's case be facilitated if raised in an individual administrative proceeding because ALJ's cannot consider such issues. The Declaratory Judgment Act and the

APA reveal congressional intent that challenges to the validity of regulations can be asserted pre-enforcement. Federal courts should exercise their traditional jurisdiction in such cases to: (a) deter administrative agencies from exceeding their legislative authority through unconstitutional rules and regulations; and (b) mitigate the widespread irreparable harm that occurs when agencies have done so.

ARGUMENT

I. CONGRESS DID NOT INTEND TO PRECLUDE INITIAL JUDICIAL REVIEW OF THE COUNCIL'S CHALLENGES TO THE SECRETARY'S REGULATIONS AND ENFORCEMENT PRACTICES.

The narrow issue before the Court is whether 42 U.S.C. § 405(h), (incorporated into the Medicare Act by 42 U.S.C. § 1395ii), which precludes initial judicial review of individual determinations regarding claims for benefits and provider status, also precludes initial judicial review of the Council's challenges to the Secretary's constitutional and statutory regulations and enforcement practices. See *McNary v. Haitian Refugee Center, Inc.*, 498 U.S. 479, 491 (1991) (defining the issue). Whether a statute is intended to preclude initial judicial review is determined from the statute's language, structure, and purpose, its legislative history, *Block v. Community Nutrition Inst.*, 467 U.S. 340, 345 (1984), and whether the claims can be afforded meaningful review. See, e.g., *Thunder Basin Coal Co. v. Reich*, 510 U.S. 200, 207 (1994); *Board of Governors, FRS v. MC Corp Financial, Inc.*, 502 U.S. 32, 43 (1991); *Whitney Nat'l Bank in Jefferson Parish v. Bank of New Orleans & Trust Co.*, 379 U.S. 411, 420-21 (1965). An examination of these factors in this case compels the conclusion that the statutory provisions at issue were not intended to preclude initial judicial review of the Council's challenges to the Secretary's regulations and enforcement practices.

A. The Plain Language of the Statutes Demonstrates That Congress Did Not Intend to Divest the Federal Courts of Initial Jurisdiction Over the Council's Challenges to the Secretary's Regulations and Practices.

In a statutory construction case, the beginning point in the analysis must be the language of the statute. *Estate of Cowart v. Nicklos Drilling Co.*, 505 U.S. 469, 475 (1992). When a statute speaks with clarity to an issue, judicial inquiry into the statute's meaning, in all but the most extraordinary circumstance, is finished. *Demarest v. Manspeaker*, 498 U.S. 184, 190 (1991).

1. Section 405(h) requires exhaustion only of individual claims for Social Security benefits.

The plain language of Section 405(h) and its companion provisions demonstrates that they pertain only to *individual* claims for *benefits* that can be raised in the administrative review process. Section 405(h) precludes review of a "decision" of the Secretary after a "hearing . . . except as herein provided." Pet. Brief App. 3a. The section 405(h) phrase "except as herein provided" in the second sentence refers to section 405(g). H.R. Rep. No. 728, 76th Cong., 1st Sess., at 43-44 (1939) (there shall be no review of the Board's decisions "except as provided in subsection (g)"). Section 405(g) in turn provides for district court review of any "final decision of the Secretary made after a hearing." The "hearing" referenced in both 405(g) and 405(h) is the administrative hearing provided in section 405(b), as the Secretary concedes. Pet. Brief 3.

The Secretary argues that section "405(h) renders the administrative and judicial review procedures under Section 405(b) and (g) exclusive." Pet. Brief 3. It is exclusive, however, only for the *types of claims* that can be brought in an administrative hearing under 405(b), namely, individual claims for benefits. This is made plain from the heading for section 405(b), which reads: "Administrative determination of *entitlement to benefits*; findings of fact; hearings;

investigations; evidentiary hearings . . ." 42 U.S.C. § 405(b) (emphasis added). App., *infra*, 1a. Section 405(b)(1) reads: "The Secretary is directed to make findings of fact, and decisions as to the rights of *any individual applying for a payment* under this subchapter." (emphasis added). Section 405(g) reads: "Any *individual*, after any final decision of the Secretary . . . made after *a hearing* . . . may obtain a review of *such decision* . . ." (emphasis added) App., *infra*, 4a. Thus, reading section 405(h) in context with 405(b) and 405(g), it is clear that 405(h) precludes only individual claims for benefits for which there is an administrative hearing and a decision by the Secretary.

The Secretary argues that Congress used the words "to recover" in some broad sense. (Pet. Brief 39 (citing dictionaries)). This argument, however, is defeated by the plain language of section 405(h) and sections 405(b) and (g). The conclusion is inescapable that section 405(h) as originally enacted pertained to individual claims for benefits for which there is an administrative hearing and final decision. Even though Congress subsequently has incorporated section 405(h) elsewhere, it still pertains to individual claims for some kind of entitlement for which there is an administrative hearing and a final decision.

The plain statutory language thus reveals that section 405(h) applies to the types of individual claims for benefits that can be raised in an administrative hearing under 405(b), and which can be reviewed on appeal by a district court under 405(g). Claims that cannot be raised in a hearing under 405(b), and that cannot be appealed under 405(g), are not subject to 405(h)'s preclusive effect. *Michigan Academy*, 476 U.S. at 478. No evidence exists in the statutory language that Congress intended that these provisions would preclude initial judicial review of statutory or constitutional challenges unrelated to individual benefits claims.

2. Medicare Act Section 1395ff requires exhaustion only of individual claims for benefits.

When Congress amended the Social Security Act in 1965 with the Medicare Act, Congress simply incorporated by reference the administrative review provisions of 405(b) and (g) via 42 U.S.C. §§ 1395ff(b) and 1395cc(h). The Medicare Act incorporates 405(h) in 42 U.S.C. § 1395ii. When Congress incorporated 405(b), (g) and (h) into Medicare, the meaning and purposes of those provisions did not change.

The plain language of 42 U.S.C. § 1395ff reveals that it also pertains only to individual claims for benefits. See 42 U.S.C. § 1395ff(a) ("The determination of whether an *individual* is entitled to *benefits* under part A or part B . . . shall be made by the Secretary . . ." (emphasis added)), App., *infra*, 5a; 42 U.S.C. § 1395ff(b)(1) ("Any *individual* dissatisfied with any determination under subsection (a) . . . shall be entitled to *a hearing* thereon . . . as is provided in section 405(b) of this title and to judicial review of the Secretary's final decision after such hearing as is provided in section 405(g) of this title." (emphasis added)), App., *infra*, 5a. Section 1395ff's purpose to provide review of individual claims for benefits is further demonstrated by the amount in controversy thresholds found in section 1395ff(b)(2)(A): "[U]nder part A of this subchapter, a hearing shall not be available to an individual . . . if the amount in controversy is less than \$100 and judicial review shall not be available to the individual . . . if the amount in controversy is less than \$1,000 . . ." App., *infra*, 6a-7a. Hence, section 1395ff pertains to individual claims for benefits.

3. Medicare Act Section 1395cc(h) requires exhaustion only of individual claims regarding provider status.

As the Secretary concedes: "If a provider wishes to dispute a determination concerning compliance or certification – or termination or non-renewal of its provider agreement – 42 U.S.C. 1395cc(h) provides that it may do so through the

hearing and review procedures under 42 U.S.C. 405(b) and (g)." Pet. Brief 4-5. Thus, section 1395cc(h) pertains to *individual* determinations regarding provider status. It speaks of "*a determination* by the Secretary that *it is not a provider* of services." App., *infra*, 9a (emphasis added). Section 1395cc(h) also references "a determination described in subsection (b)(2) of this section." *Id.* Subsection (b)(2), in turn, includes among other things, a refusal to enter into a provider agreement with, or termination of such an agreement with an individual provider. See §§ 1395cc(b)(2); App., *infra*, 8a-9a. The language of sections 1395cc(b)(2) and (h), therefore, plainly demonstrates that they pertain to *individual* provider status claims.

B. The Legislative History Confirms That Congress Did Not Intend to Divest the Federal Courts of Initial Jurisdiction Over Constitutional and Statutory Challenges to the Secretary's Regulations.

The 1939 legislative history pertaining to sections 405(b), (g) and (h) is consistent with the plain language of the statutes. This Court has repeatedly looked to a statute's legislative history as an aid to determining its meaning, and has recognized the reliability of committee reports from the earlier part of this century. See, e.g., *Wisconsin Public Intervenor v. Mortier*, 501 U.S. 597, 610 (1991) ("Our precedents demonstrate that the Court's practice of utilizing legislative history reaches well into its past. We suspect that the practice will likewise reach well into the future."); *Thornburg v. Gingles*, 478 U.S. 30, 44, n.7 (1986) ("We have repeatedly recognized that the authoritative source for legislative intent lies in the Committee Reports on the bill."); *Garcia v. United States*, 469 U.S. 70, 76-77 (1984), *reh'g denied*, 469 U.S. 1230 (1985) (relying on 1935 Committee Reports to examine congressional intent); *Michigan Academy*, 476 U.S. at 676-78 (relying on 1965 Committee Reports).

The Senate Report prefaces its discussion of section 405 by stating, "[t]his section of the bill provides a detailed procedure in connection with *benefit determination and*

payment." S. Rep. No. 734, 76th Cong., 1st Sess., at 51 (1939) (emphasis added). It states that section 405(b) "outlines the general functions of the Board in determining *rights to benefits*. It requires the Board to offer opportunity for a hearing, upon request, *to an individual* whose rights are prejudiced by any decision of the Board." *Id.* (emphasis added). After stating that 405(g) allows judicial review of a final administrative decision, the report notes that "[t]he present provisions of the Social Security Act do not specify what remedy, if any, is open to *a claimant* in the event *his claim to benefits* is denied by the Board." *Id.* at 52 (emphasis added). Statements in the House Report regarding section 405 are virtually identical to the above report of the Senate. See H.R. Rep. No. 728, 76th Cong., 1st Sess., at 42-44 (1939). Compare *Weinberger v. Salfi*, 422 U.S. 749, 792, n.8 (1975) (Brennan, J., dissenting): "[A]t their inception, the exhaustion provisions which became §§ 405(g) and (h) were clearly intended to apply only to run-of-the-mill claims under the statutory provisions, in which factual determinations would be paramount").

Similarly, the legislative history of section 1395ff confirms that section 1395cc(h) pertains to individual provider status claims. Section 1395cc(h) originally appeared at 42 U.S.C. § 1395ff(c). See 42 U.S.C. § 1395ff(c) (1976); see also Pet. Brief 5, n.3. The legislative history of section 1395ff states that current section 1395cc(h) provided hospitals, extended care facilities, and home health agencies with a hearing and judicial review "if they are dissatisfied with the Secretary's determination regarding their eligibility to participate in the program." S. Rep. No. 404, 89th Cong., 1st Sess., pt. I, at 55 (1965); H.R. Rep. No. 213, 89th Cong., 1st Sess., at 47 (1965). Section 1395cc(h) thus pertains to individual provider status claims. No evidence exists that Congress intended section 1395cc(h) to prohibit broad statutory or constitutional challenges to regulations.

The Secretary relies heavily on a single sentence in a Senate Report from the Medicare Act's 1965 legislative history which reads: "It is intended that the remedies provided by these

review procedures *shall be exclusive.*" Pet. Brief 22 (emphasis added). That sentence does not appear in the companion House Report. See H.R. No. 213, 89th Cong., 1st Sess., at 47 (1965). Moreover, the Secretary ignores the context of the paragraph. The full paragraph shows that the "review procedures" pertain to "individual" claims for benefits or provider status:

The committee's bill provides for the Secretary to make determinations, under both the hospital insurance plan and the supplementary plan, as to whether *individuals* are entitled to hospital insurance *benefits* or supplementary medical insurance *benefits* and for hearings by the Secretary and judicial review where an *individual* is dissatisfied with the Secretary's determination. Hearings and judicial review are also provided for where an *individual* is dissatisfied with a *determination* as to the *amount of benefits* under the hospital insurance plan if the amount in controversy is \$1,000 or more. (Under the supplementary plan, carriers, not the Secretary, would review beneficiary complaints regarding the *amount of benefits*, and the bill does not provide for judicial review of a *determination* concerning the *amount of benefits* under part B where claims will probably be for substantially smaller amounts than under part A.) Hospitals, extended care facilities, and home health agencies would be entitled to hearing and judicial review if they are dissatisfied with the Secretary's *determination regarding their eligibility to participate* in the program. It is intended that the remedies provided by these review procedures shall be exclusive.

S. Rep. No. 404, 89th Cong., 1st Sess., pt. 1, at 54-55 (1965) (emphasis added).

The sentence the Secretary quotes is no evidence that collateral statutory and constitutional claims are barred by section 405(h). The Senate Report shows only an intent to provide review of individual claims for benefits or provider status, and not any intent to exclude initial jurisdiction over

collateral statutory and constitutional challenges.

C. The Broader Statutory Scheme Confirms That Congress Did Not Intend To Divest The Federal Courts of Jurisdiction Over Constitutional And Statutory Challenges to the Secretary's Regulations.

The Seventh Circuit's construction of the statutory provisions at issue is consistent with a broader scheme of relevant statutes. Passage of the federal declaratory judgment statute in 1934 confirmed Congress' intent that declaratory judgment actions could be used to test the validity of federal laws. Congress believed declaratory judgment actions would be used avoid the "social and economic waste and destruction" from having "to violate or purport to violate a statute in order to obtain a judicial determination of its meaning or validity . . ." S. Rep. No. 1005, 73rd Cong., 2d. Sess., at 2-3 (1934). Five years later, in 1939, Congress amended the Social Security Act with the administrative and judicial review provisions of 42 U.S.C. § 405(b), (g) and (h) for individual benefits claims, but took no steps to withdraw traditional remedies in federal court for challenging the validity of regulations.

Seven years later, in 1945, Congress passed the Administrative Procedure Act ("APA"). The legislative history of the APA says that "[i]t has never been the policy of Congress to prevent the administration of its own statutes from being judicially confined . . . for in such a case statutes would in effect be blank checks drawn to the credit of some administrative officer or board." S. Rep. No. 752, 79th Cong., 1st Sess., at 26 (1945). Congress specifically provided in 5 U.S.C. § 703 that in the "absence or inadequacy" of a special statutory review proceeding, "any applicable form of legal action, including actions for declaratory judgments or writs of prohibitory or mandatory injunction or habeas corpus, [is available] in a court of competent jurisdiction . . ." The legislative history to section 703 further reveals that both houses of Congress agreed that *pre-enforcement* declaratory judgment actions would continue to be used to test the validity of statutes:

Declaratory judgment procedure, for example, may be operative before statutory forms of review are available and may be utilized to determine the validity or application of any agency action. By such an action the court must render a judicial declaration of rights, and so bind an agency upon the case stated and in the absence of a reversal.

H.R. Rep. No. 1980, 79th Cong., 2d. Sess., at 42 (1946); accord S. Rep. No. 752, 79th Cong., 1st Sess., at 26 (1945). Section 405(h) should be viewed in context with the Declaratory Judgment Act and the APA where Congress expressed its intent that jurisdiction would exist for pre-enforcement challenges to the validity of agency action. The Secretary's construction of 405(h) conflicts with those seminal acts.

D. The Secretary's Statutory Construction Would Deny Meaningful Judicial Review.

The Secretary argues that *Michigan Academy* does not support initial jurisdiction in this case because section 405(g) expressly confirms the district court's power to "review . . . the validity of . . . [the Secretary's] regulations" when it reviews the Secretary's final decision. Pet. Brief 47. However, if a district court cannot meaningfully review the validity of the Secretary's general regulations and practices, no exhaustion is required. *McNary*, 498 U.S. at 498-99.

In fact, the Secretary's position is undermined by "the strong presumption that Congress intends judicial review of administrative action." *Michigan Academy*, 476 U.S. at 670. See also, e.g., *Barlow v. Collins*, 397 U.S. 159, 166-67 (1970); *Dunlop v. Bachowski*, 421 U.S. 560, 567 (1975); *Traynor v. Turnage*, 485 U.S. 535, 540 (1988); *Reno v. Catholic Soc. Servs.*, 509 U.S. 43, 63-64 (1993). These principles have been invoked time and again when considering whether the Secretary has discharged her "heavy burden" of overcoming the "strong presumption" of meaningful judicial review. *Michigan Academy*, 476 U.S. at 671-72 (quoting *Dunlop v. Bachowski*, 421 U.S. 560, 567 (1975)). See also, Louis Jaffe, *The Right to*

Judicial Review I, 71 Harv. L. Rev. 401, 432 (1958) ("[J]udicial review is the rule. It rests on the congressional grant of general jurisdiction to the Article III courts. It is a basic right; it is a traditional power and the intention to exclude it must be made specifically manifest."). The presumption of review is the starting point, and only upon a showing of clear and convincing evidence is it overcome. *Michigan Academy*, 476 U.S. at 670 ("We begin with the strong presumption") (emphasis added); *McNary*, 498 U.S. at 498-99 ("strong presumption . . . is not overcome by the language or the purpose of the relevant provisions of the Reform Act."). In *McNary*, this Court applied the strong presumption even though a review mechanism existed for individual SAW claims whereby a claimant could appeal to a circuit court. 498 U.S. at 485-86, 498-99. Thus, the strong presumption exists even when some review is provided for certain types of claims, because the review provided may be inadequate for the types of claims at issue.⁹ See 5 U.S.C. § 703 (in the absence or inadequacy of a special statutory review proceeding any applicable form of legal action is available).

Under the Secretary's interpretation of the statute, the Council would not be able to obtain meaningful judicial review of its constitutional and statutory claims if it is forced to submit to the administrative review process. On its face, section 405(g) limits the scope of the district court's review to the administrative record, and gives "power to enter, upon the pleadings and transcript of the record, a judgment affirming, modifying, or reversing the decision of the Commissioner of Social Security, with or without remanding the cause for a rehearing." Pet. Brief App. 1a. Obviously, if the Secretary has

⁹ The Secretary erroneously relies on *Thunder Basin Coal Company v. Reich*, 510 U.S. 200 (1994) for the contention that the presumption does not apply here because there is post-enforcement judicial review of the Council's claims. In *Thunder Basin*, this Court declined to apply the presumption because there was meaningful "court of appeals review" of the relevant claims. 510 U.S. at 207 n.8, 212-214. Here, there is no meaningful post-enforcement federal court review of the Council's claims. See *McNary*, 498 U.S. at 498 (applying presumption where post-enforcement judicial review was not meaningful).

provided no "hearing" in which to adjudicate constitutional or statutory claims, there will be no "final decision" and no administrative record regarding such claims for a court to "affirm, modify or reverse." See *Michigan Academy*, 476 U.S. at 679, n.8. Administrative law judges lack authority to hear statutory or constitutional challenges to regulations.¹⁰ The Secretary admits that "[n]either the Departmental Appeals Board nor individual ALJs are free to depart from statutory and regulatory requirements." Pet. Brief 45. Moreover, section 405(g) "contains no suggestion that a reviewing court is empowered to enter an injunctive decree whose operation reaches beyond the particular applicants before the court." *Weinberger v. Salfi*, 422 U.S. 749, 763, n.8 (1975).

Furthermore, the Secretary exaggerates the scope of a district court's powers in a section 405(g) appeal. The plain language of section 405(g) reveals that the "regulations" that can be reviewed pertain to an individual's burden of proof to establish his claim to benefits, rather than the agency's regulations and practices generally. The "regulations" referred to in section 405(g) are regulations promulgated under section 405(a), which requires the Secretary to establish rules and regulations for processing individual claims for benefits. Section 405(g) reads in pertinent part:

where a claim has been denied by the Commissioner of Social Security or a decision is rendered under subsection (b) of this section which is adverse to an individual who was a party . . . because of failure of the claimant or such individual to submit proof in conformity with any regulation prescribed under subsection (a) of this section, the court shall review only the question of conformity with such regulations and the validity of such regulations.

App., *infra*, 4a (emphasis added). Contrary to the Secretary's

contentions, section 405(g)'s language shows that Congress intended section 405(g) courts to review individual claims and "such regulations" that bear on whether an individual has met his burden of proof in the specific individual hearing being reviewed. Indeed, a precondition to reviewing the validity of the regulation is an individual's failure to submit proof in such a hearing. The plain language does not establish that Congress intended section 405(g) courts to review broad statutory and constitutional challenges unrelated to an individual claim for benefits. Moreover, the legislative history of section 405(g) confirms this. It reads in pertinent part: "Where a decision of the Board is based on a failure to submit proof in conformity with a regulation, the court may review only the question of *conformity of the proof with the regulation* and the validity of *the regulation*." H.R. Rep. 728, 76th Cong., 1st Sess., at 43 (1939); Accord S. Rep. No. 734, 76th Cong., 1st Sess., at 51 (1939) (emphasis added). The legislative history gives no indication that Congress was considering statutory or constitutional challenges to regulations generally.

This Court rejected in *McNary* the Secretary's argument that constitutional and statutory claims adequately can be "deferred." In *McNary*, the Immigration and Naturalization Act ("INA") provided for administrative review and thereafter judicial review by the court of appeals regarding decisions on amnesty applications. This Court concluded that the limited post-exhaustion judicial review provided could not adequately address the statutory and constitutional claims at issue. *McNary*, 498 U.S. at 484, 496-97. Administrative and judicial review of an agency decision "is almost always confined to the record made in the proceeding at the initial decisionmaking level . . ." *Id.* at 496. The lack of an adequate administrative record at the initial decision making level meant that the court of appeals would have no "meaningful basis upon which to review application determinations." *Id.* By contrast, a district court exercising section 1331 jurisdiction as a trial court with its "fact finding and record-developing capabilities," is an adequate forum for challenges to the validity of regulations. *Id.* at 497.

¹⁰ E.g., *Bowen v. Michigan Academy of Family Physicians*, 476 U.S. 667, 676, n.6 (1986); *American Ambulance Service, Inc. v. Sullivan*, 911 F.2d 901, 905 (CA3 1990), aff'd without opinion, 947 F.2d 934 (CA3 1991); 42 C.F.R. § 1005.4(c)(1), (4).

The same analysis applies here. In a section 405(g) appeal, the district court is limited to the administrative record of a hearing. The Council's statutory and constitutional claims cannot be considered in an administrative hearing. There accordingly would be no evidence taken and no administrative record compiled regarding the Council's statutory and constitutional claims for a federal court to review in a 405(g) appeal. As in *McNary*, restricting judicial review to the limited scope of section 405(g) "is the practical equivalent of total denial of judicial review of generic constitutional and statutory claims." *Id.* at 497. Therefore, even if Congress did intend to preclude all review of statutory and constitutional claims until a 405(g) appeal, which it did not, section 1331 jurisdiction is available because a district court in a 405(g) appeal is an inadequate forum.

Practical considerations of cost and delay in the administrative process further underscore the inadequacy of the Secretary's review scheme. Administrative appeal rights are triggered only by imposition of a "remedy." See 42 C.F.R. § 498.3(b)(12). If a provider cures the alleged deficiency before a remedy is imposed, it loses its appeal rights. Thus, when an inspection results in deficiencies, a provider must choose between: (a) refusing to correct the alleged deficiency and risking termination of its provider agreement in order to appeal the deficiency; or (b) remedying the alleged deficiency and thereby forfeiting appeal rights. Providers rarely refuse to comply just so that they can appeal. Because nursing facilities generally "knuckle under" rather than appeal, challenges to the validity of a regulation will rarely, if ever, reach the 405(g) appeal stage.

For this reason, the Secretary's argument that "post-enforcement review" is available and adequate rings hollow. During the first six months after the effective date of the 1995 Regulations, literally thousands of nursing homes had sanctions proposed against them. But only 3.6% of those providers received a penalty such that any *administrative*

review was available, much less judicial review.¹¹ This fact belies the Secretary's argument that a 405(g) appeal is adequate for statutory and constitutional claims. The Secretary's proposed system simply does not work for statutory and constitutional claims. For over four years, the Secretary has had the kind of "blank check" that Congress deplores. S. Rep. No. 752, 79th Cong., 1st Sess., at 26 (1945); H.R. Rep. No. 1980, 79th Cong., 2d. Sess., at 41 (1946).

The Secretary also contends that other provisions of the Medicare Act, like 42 U.S.C. §§ 1395cc(f)(1) and 1395ff(b)(3), provide a mechanism for meaningful review of the Council's claims. Pet. Brief 47-48. The Secretary ignores, however, that section 1395oo(f)(1) "certification" by the Provider Reimbursement Review Board (PRRB) is not available here because the Council is not a provider bringing a reimbursement claim. Nor does the Council's suit raise "national coverage decisions" within the meaning of section 1395ff(b)(3). Pet. Brief 47-48. Thus, the provisions relied on by the Secretary provide no mechanism available to the Council for meaningful review of its statutory and constitutional challenges to the Secretary's regulations and enforcement practices.

Because the statutory scheme does not permit meaningful post-enforcement review of the Council's claims, the Secretary's position boils down to the obviously untenable contention that there is no federal court review of the constitutionality of rules and regulations that the Secretary herself enacted. The Constitution does not permit the fox to guard the hen house in this manner, but instead ensures that the federal judiciary will be the ultimate arbiter of the legitimacy of administrative rulemaking action. *Gutierrez De Martinez v. Lamagno*, 515

¹¹ Between July 1, 1995 and January 1, 1996, there were 21,351 nursing home surveys (8711 "standard surveys" plus 12,640 "complaint surveys"). J.A. 77; Brief of Amicus Curiae American Association of Homes and Services for the Aging 18 (AAHSA Brief). Penalties were proposed in 14,386 of these cases. J.A. 78; AAHSA Brief at 18. Of these, a sanction was imposed in only 523 cases (3.6%), triggering the provider's administrative appeal right.

U.S. 417, 424 (1995) (quoting *United States v. Nourse*, 34 U.S. (9 Pet.) 8, 28-29 (1835)). For that reason, there must be clear and convincing evidence of legislative intent for a court to restrict access to meaningful judicial review. *Lindahl v. Office of Personnel Management*, 470 U.S. 768, 779 (1984). "[O]nly upon a showing of 'clear and convincing evidence' of a contrary legislative intent should the courts restrict access to judicial review." *Abbott Laboratories v. Gardner*, 387 U.S. 136, 141 (quoting *Rusk v. Cort*, 369 U.S. 367, 379-80 (1961)); see also *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 410 (1970); *Johnson v. Robison*, 415 U.S. 361, 373-74 (1974); *Gutierrez De Martinez v. Lamagno*, 515 U.S. 417, 424 (1995); H.R. Rep. No. 1980, 79th Cong., 2d. Sess., at 41 (1946) ("To preclude judicial review . . . a statute, if not specific in withholding such review, must upon its face give clear and convincing evidence of an intent to withhold it.").

Here, the Secretary has identified no evidence – either from the plain language of the statutes, the pertinent legislative history or from any other source -- that Congress intended to deprive the federal courts of plenary jurisdiction over the types of constitutional and statutory challenges brought by the Council here. Rather, the evidence points unmistakably to the conclusion that the exhaustion of administrative remedies is not a precondition to federal court review of these claims.

E. Properly Construed, the Statutes Afford Initial Judicial Review Over the Council's Claims As Set Forth In Its Amended Complaint.

The Amended Complaint alleges no individual provider status claim and makes no individual benefits claim. The Council asserts a facial challenge to statutory procedures and practices. The Council contends: (a) that the 1995 Regulations are unconstitutionally vague; (b) that the 1995 Regulations and SOM violate the APA; (c) that the administrative review

mechanism of the 1995 Regulations is so restrictive that it violates due process; and (d) that the Secretary has failed to take adequate steps to reduce inconsistency in survey results in violation of the Social Security Act. See J.A. 17-19, 51-52.

This Court has long embraced the view that statutory or constitutional challenges to a regulation or policy, like those asserted by the Council in this case, are collateral to a substantive claim of entitlement, and that federal courts have jurisdiction for such claims. See *Johnson v. Robison*, 415 U.S. at 373 (jurisdiction exists for action challenging constitutionality of veterans benefits legislation); *Abbott Laboratories v. Gardner*, 387 U.S. at 148 (jurisdiction exists for pre-enforcement review of pharmaceutical regulations); *Mathews v. Eldridge*, 424 U.S. 319, 330-32 (1976) (upholding federal question jurisdiction over systemic and constitutional challenge to administrative procedures established by the Secretary); *Bowen v. New York*, 476 U.S. 467, 483-86 (1976); *Michigan Academy*, 476 U.S. at 670; *McNary*, 498 U.S. at 497-98. This Court has thus recognized that there is a difference between a collateral constitutional challenge and an individual claim of entitlement. E.g., *Mathews*, 424 U.S. at 330-31.

To illustrate, the class action complaint in *McNary* alleged that the INS had engaged in unlawful practices and policies in administering one of its programs and that the interview process was arbitrary, depriving applicants of due process. 498 U.S. at 487-88. This Court held that the claim was collateral to any individual determination of an application. *McNary*, 498 U.S. at 492; see also *id.* at 497-98 ("[in *Michigan Academy*] [w]e recognized that review of individual determinations of the amount due on particular claims was foreclosed, but upheld the *collateral attack* on the regulation itself, emphasizing the critical difference between an individual 'amount determination' and a challenge to the procedures for making such determinations. . . ."). (emphasis added) See also *Bowen v. New York*, 476 U.S. at 483 ("[t]he claims in this lawsuit are collateral to the claims for benefits . . . [t]he class members neither sought nor were awarded benefits in the

District Court, but rather challenged the Secretary's failure to follow the applicable regulations.").

Likewise, the Council facially attacks certain aspects of the enforcement program, allegations which are "beyond the scope of administrative review." *McNary*, 498 U.S. at 488. The Council's lawsuit falls squarely within this Court's precedents recognizing jurisdiction over collateral challenges. Sections 405(g) and (h) are tailored to individual determinations and do not refer to general collateral challenges. *Id.* at 492-93.

The Secretary's position is based on the erroneous contention that the Council is asserting a claim for benefits, and that therefore the Council's claims are "indistinguishable" from those asserted in *Ringer* and *Salfi*. Pet. Brief 42. However, as this Court has concluded before, *Ringer* and *Salfi* have no bearing on the issues here. In *Ringer* itself, this Court characterized the claims "essentially as claims for benefits." *Heckler v. Ringer*, 466 U.S. 602, 609, n.4 (1984). In *McNary* this Court discussed *Ringer* at length and found that it did not apply. *McNary*, 498 U.S. at 494-96 (concluding that claims in *Ringer* were claims for benefits). In *Michigan Academy*, this Court clarified that in *Ringer* the preclusion of judicial review was not extended beyond the Part B "amount determinations" at issue there. *Michigan Academy*, 476 U.S. at 677, n.7. The Secretary's claim that the Seventh Circuit's reading of *Michigan Academy* is in "irreconcilable conflict" with *Ringer* is hyperbole, because *Ringer* is not relevant to the issue here. Pet. Brief 34.

Likewise, in *Weinberger v. Salfi*, this Court referred to "suits, such as this one, which seek to recover Social Security benefits." 422 U.S. at 757. In describing the proceedings below, this Court noted that the district court granted a judgment "directing the Secretary to pay Social Security benefits." *Id.* at 761. *Salfi*, therefore, addressed only the availability of judicial review of an individual benefits determination. In contrast with *Ringer* and *Salfi*, the Council is not pursuing an individual benefits claim, just as in *McNary*,

New York, Michigan Academy and Reno. Indeed, it is difficult to imagine how claims could be more "collateral" than the Council's here.

The Secretary also cites *United States v. Erika, Inc.*, 456 U.S. 201 (1982), contending that review mechanisms are exclusive. Pet. Brief 24. However, the respondent in *Erika* was asserting a "claim for benefits." It argued that reimbursement under Part B for certain medical supplies should be based on the cost of the goods sold, including recent price increases. *Erika*, 456 U.S. at 204-05. The carrier instead used the price in its catalog as of July 1 of the previous calendar year. *Id.* at 209. After an unsuccessful hearing before the carrier, respondent filed suit in the U.S. Court of Claims. The Court of Claims accepted jurisdiction and found in respondent's favor on the merits. *Id.* This Court reversed, concluding that the Court of Claims lacked jurisdiction.

After analyzing the statutory provisions and the legislative history of the Medicare Act, this Court concluded that Congress intended to preclude jurisdiction over amounts determinations under Part B. *Erika*, 456 U.S. at 208. This Court quoted several statements in the legislative history whereby Congress clarified its determination that Part B amounts determinations were too insignificant for administrative and judicial review. *Id.* at 208-9. Significantly, respondent did not assert any constitutional or statutory challenges to the applicable regulations before this Court. Thus *Erika* is immaterial to the Council's collateral constitutional and statutory challenges.

Equally misplaced is the Secretary's reliance on this Court's recent decision in *Your Home Visiting Nurse Services, Inc. v. Shalala*, 119 S. Ct. 930 (1999). See Brief in Opp. 7-9. In that case, this Court held that the Provider Reimbursement Review Board ("PRRB") lacked jurisdiction to review a fiscal intermediary's refusal to reopen a reimbursement determination. This Court rejected petitioner's "fallback argument" that judicial review of the refusal to reopen was available under either

section 1331, mandamus or the APA's judicial review provision. *Your Home*, 119 S. Ct. at 935-36. The petitioner in *Your Home* was seeking reimbursement of certain Medicare claims upon "new and material evidence." *Id.* at 933. It was not asserting a collateral constitutional or statutory claim. Of course, the Secretary is not blind to the difference between an individual claim for benefits and a collateral attack to the validity of a regulation. As the Secretary recognized in her merits brief in *Your Home*:

[Petitioner's claim] does not attack the underlying validity of a regulation; it simply avers that the intermediary misapplied a regulation when determining the amount of reimbursable owners' compensation costs owed to petitioner. Thus, petitioner's contentions do not resemble the sort of facial challenge that the Court in *Michigan Academy* found to be beyond the scope of Section 405(h)'s preclusive effect.

Your Home Visiting Nurse Services, Inc. v. Shalala, Resp. Brief at 31, 1998 WL 644663.

The fallacy of the Secretary's "claim for benefits" argument is more apparent when considering that the Council, a trade association, has no access at all to the Secretary's administrative review mechanism. Because of its status, the Council could not assert a claim for benefits even if it wanted to. The Council likewise is not a "provider of services" that has or seeks a provider agreement within the meaning of 42 U.S.C. § 1395cc(h). On their face, therefore, the administrative review provisions of the Medicare Act do not apply to the Council.

Because the Council has no access to the administrative review process, section 405(h) does not bar its claims. *Michigan Academy of Family Physicians v. Blue Cross and Blue Shield of Michigan*, 757 F.2d 91, 94 (CA6 1985), aff'd, *Michigan Academy*, 476 U.S. 667 (1986). In *Michigan Academy*, this Court granted certiorari twice. "We first granted . . . certiorari to allow the Court of Appeals to consider its jurisdictional ruling in light of *Heckler v. Ringer*." *Michigan*

Academy, 476 U.S. at 669, n.2. On remand, the Sixth Circuit specifically addressed whether the academy of physicians, a non-profit corporation, was entitled to challenge the regulation at issue since section 405(g) was not available to it, as it was to individual claimants. The Sixth Circuit held that *Heckler v. Ringer* did not proscribe review where challenge is made by a party other than a claimant for benefits. *Michigan Academy of Family Physicians*, 757 F.2d at 94. This Court affirmed in *Bowen v. Michigan Academy of Family Physicians*, 476 U.S. 667 (1986) ("[The Association's] attack on the regulation here is not subject to [an exhaustion] requirement because there is no hearing, and thus no administrative remedy, to exhaust."). *Id.* at 679, n.8.

Similarly in *Rosado v. Wyman*, 397 U.S. 396 (1970), *reh'g denied*, 398 U.S. 914 (1970), this Court held that exhaustion was inapplicable where petitioners could not have obtained an administrative ruling because "HEW has no procedures whereby welfare recipients may trigger and participate in the Department's review of state welfare programs." *Id.* at 406 (citing *Abbott Laboratories*, 387 U.S. 136). See also *Nader v. Alleghany Airlines, Inc.*, 426 U.S. 290, 302 (1976) (individual consumers are not entitled to initiate administrative proceedings, which indicates that Congress did not intend to require consumers to exhaust before proceeding with common law remedies). The same reasoning applies here. The Secretary's contention that the Council is seeking to "bypass the express statutory mechanisms for judicial review provided by the Medicare Act" is insupportable. See Pet. Brief 26-27.

II. MICHIGAN ACADEMY AND McNARY COMPEL AFFIRMANCE OF THE DECISION BELOW.

A. Michigan Academy

1. Michigan Academy Rejects Arguments Made By the Secretary Here.

In *Michigan Academy*, this Court confronted and rejected many of the Secretary's arguments here. *Michigan Academy* involved a challenge to the validity of a regulation by a trade association of physicians. The regulation authorized the payment of benefits in different amounts for similar physicians' services. *Michigan Academy*, 476 U.S. at 668. However, the lower courts struck down the regulation. On certiorari, the Secretary contested jurisdiction. The Secretary argued that Congress precluded federal question jurisdiction through 42 U.S.C. §§ 1395ff and 1395ii (which incorporates section 405(h)). *Id.* at 668. This Court considered the language and legislative history of both sections 1395ff (see *id.* at 674-678) and 1395ii (*id.* at 678-681). This Court held that federal question jurisdiction existed and affirmed the lower courts. Those same statutes, particularly section 1395ii and section 405(h), are at issue here.

The Secretary contended in *Michigan Academy* that section 1395ff(b) "impliedly" foreclosed administrative or judicial review of any action taken under part B. 476 U.S. at 674. This Court disagreed:

Section 1395ff on its face is an explicit authorization of judicial review, not a bar. As a general matter, "[the] mere fact that some acts are made reviewable should not suffice to support an implication of exclusion as to others. The right to review is too important to be excluded on such slender and indeterminate evidence of legislative intent."

Id. at 674 (quoting *Abbott Laboratories*, 387 U.S. at 141 (citations omitted)). Significantly, when *Michigan Academy* was decided, section 1395cc(h), which authorizes administrative review under section 405(g) of individual provider status claims, was included within section 1395ff at subsection (c). See Pet. Brief 5, n.3. Thus, this Court's analysis of section 1395ff in *Michigan Academy* is probative of congressional intent regarding section 1395cc(h). See 476 U.S. at 680, n.10 ("[I]t bears mention that the legislative history

summarized in the preceding section speaks to provisions for appeal generically, and is thus as probative of congressional intent in enacting § 1395ii as it is of § 1395ff." (citing legislative history)).

This Court recognized in *Michigan Academy* that judicial review existed because certain claims cannot be considered during the administrative review process. 476 U.S. at 676 ("the legality, constitutional or otherwise, of any provision of the Act or regulations relevant to the Medicare Program is not considered in a "fair hearing" held by a carrier to resolve a grievance related to a determination of the amount of a Part B award."). The same applies here. Administrative law judges, like the hearing officers in *Michigan Academy*, cannot use "hearing decisions as a vehicle for commenting upon the legality, constitutional or otherwise, of any provision of the Act or regulations relevant to the Medicare Program." *Id.* at 667, n.6. This Court concluded that "matters which Congress did not leave to be determined in a 'fair hearing' conducted by the carrier--including challenges to the *validity* of the Secretary's instructions and regulations--are not impliedly insulated from judicial review by 42 U.S.C. 1395ff." *Id.* at 678.

This Court in *Michigan Academy* also construed the language and legislative history of sections 1395ii and 405(h). This Court rejected the Secretary's contention that sections 1395ii and 405(h) bar challenges to regulations. As she does here, the Secretary relied heavily on the "arising under" analysis of *Ringer* and *Salfi*. 476 U.S. at 679. This Court declined to apply the "abstract" and over-simplified "arising under" analysis and instead relied on the language and legislative history of the statutes:

Whichever may be the better reading of *Salfi* and *Ringer*, we need not pass on the meaning of § 405(h) in the abstract to resolve this case. . . . The legislative history of both the statute establishing the Medicare program and the 1972 amendments thereto provides specific evidence of Congress' intent to foreclose review only of "amount

determinations" -- i.e., those "quite minor matters," remitted finally and exclusively to adjudication by private insurance carriers in a "fair hearing." By the same token, matters which Congress did not delegate to private carriers, such as challenges to the validity of the Secretary's instructions and regulations, are cognizable in courts of law. 476 U.S. at 680.

This Court further rejected the Secretary's argument that a challenged regulation is a "decision of the Secretary" which the second sentence of section 405(h) excepts from review. 476 U.S. at 674, n.8. This Court stated that such an argument "ignores the contextual definition of 'decision' in the first sentence as those determinations made by the Secretary after a hearing." *Id.* Clearly, the Council here is *not* challenging through this lawsuit a "decision" of the Secretary after a "hearing." The Secretary holds no "hearings" to determine the constitutionality of her regulations. This Court also rejected the Secretary's contention that its decision would "open the floodgates." *Id.* at 681, n.11. This Court recognized that permitting review only of a particular statutory or administrative standard would not result in a costly flood of litigation, because the validity of a standard can be readily established, at times even in a single case. *Id.* (quoting Note, 97 Harv. L. Rev. 778, 792 (1984)).

The Seventh Circuit below simply followed, in straightforward fashion, this Court's interpretation of particular statutes and their legislative history in *Michigan Academy*. The Seventh Circuit declared: "As the Court read § 1395ii and therefore § 405(h) in *Michigan Academy*, pre-enforcement review of a regulation's validity is not an action to 'recover on' a claim, even when per *Salfi* a constitutional objection to the regulation is a 'claim arising under this subchapter.'" Pet. App. 6a. As its opinion indicates, the Seventh Circuit carefully considered *Salfi* and *Ringer*, but it chose to follow the more recent and more precise holding of *Michigan Academy*.

2. The Secretary's Attempt To Avoid *Michigan Academy* Does Not Survive Scrutiny.

In an attempt to avoid *Michigan Academy*, the Secretary argues that the case lost value as precedent soon after it was decided because of Medicare amendments passed as part of the Omnibus Budget Reconciliation Act of 1986 (OBRA 86), Pub. L. No. 99-509, § 9341, 100 Stat. 2037-38. Pet. Brief 36-37. This argument is meritless, as the Seventh Circuit concluded. This Court often has relied on *Michigan Academy* even after the 1986 OBRA amendments. Moreover, both the textual changes to 42 U.S.C. § 1395ff in 1986 and the legislative history reveal that the amendments did not alter the force and viability of *Michigan Academy*'s reasoning and holding. Contrary to the Secretary's contentions, the Seventh Circuit's conclusion regarding the vitality of *Michigan Academy* is not an anomaly. See Pet. Brief 33-34.

Two years after *Michigan Academy* (and after the 1986 amendments), this Court repeatedly quoted from *Michigan Academy* in *Traynor v. Turnage*, 485 U.S. 535 (1988), concluding that jurisdiction existed for a challenge over whether a Veteran's Administration regulation violated the Rehabilitation Act. 485 U.S. at 543. Five years after *Michigan Academy*, this Court revisited its holding in *McNary v. Haitian Refugee Center, Inc.*, 498 U.S. 479 (1991), and confirmed that federal question jurisdiction existed over systemic and constitutional challenges to regulatory procedures under the Immigration Reform and Control Act of 1986 ("IRCA").

Since 1991, this Court has approved the holdings of *Michigan Academy* and *McNary* in other cases, including *Reno v. Catholic Social Services, Inc.*, 509 U.S. 43, 64 (1993) (following *McNary* and citing to *Michigan Academy*); *Thunder Basin Coal Company v. Reich*, 510 U.S. 200, 213-14 (1994) (citing *Michigan Academy* and discussing but distinguishing *McNary*); and *Gutierrez De Martinez v. Lamagno*, 515 U.S. 417, 424 (1995) (citing *Michigan Academy*). Hence, *Michigan Academy* has retained its precedential value and the Seventh

Circuit was obliged to follow it.

The amendments upon which the Secretary relies to avoid the holding of *Michigan Academy* were adopted as part of OBRA 86. The amendments granted Part B claimants the same hearing and appeal rights previously enjoyed by Part A claimants, subject to certain amount-in-controversy restrictions. They remedied a gap in judicial review for individual benefit claims recognized in *United States v. Erika, Inc.*, 456 U.S. 201 (1982).

As the Seventh Circuit explained, OBRA 86 did not amend either section 405(h) or 1395ii. The amendments, on their face, granted only *greater* judicial review to certain Part B claims and certainly did not expressly take jurisdiction away regarding other claims. The legislative history confirms this. The House Report explains why Part B claimants had not previously enjoyed administrative and judicial review (in large part because of the volume and small amounts of money involved). It then concludes that additional review nevertheless is necessary because of concerns regarding the fairness and adequacy of carrier "fair hearings." H.R. Rep. No. 99-727, at 95 (1986), reprinted in 1986 U.S.C.C.A.N. 3607, 3685. Similarly, the Conference Report only addresses judicial review of coverage determinations. It does not address statutory or constitutional challenges to regulations. H.R. Conf. Rep. No. 99-1012, at 350 (1986), reprinted in 1986 U.S.C.C.A.N. 3868, 3995. The author of the Medicare amendments stated that: "[t]his legislation strengthens the rights established by the Supreme Court in its decision, *Bowen* versus *Michigan Academy of Family Physicians*, earlier this year. And it ensures that beneficiaries and providers who feel wronged by Medicare's decisions have access to appeal." 132 Cong. Rec. E3799 (1986) (statement of Rep. Ron Wyden) (emphasis added). This statement demonstrates an intent to provide *additional* protection (administrative and judicial) to what this Court recognized in *Michigan Academy*.

This Court encountered a similar situation in *Lindahl v. Office of Personnel Management*, 470 U.S. 768 (1984). There, this Court held that an amendment to a statute did not eliminate judicial review: "There is certainly nothing on the face of the . . . amendment suggesting that Congress intended to discard [judicial] review generally while expanding upon it in a particular category of cases." *Lindahl*, 470 U.S. at 782. This Court further stated that "[i]f Congress had intended by the 1980 amendment not only to expand judicial review . . . but to abolish the standard in all other cases as well, there would presumably be some indication in the legislative history to this effect." *Id.* at 787. The same rationale applies here. There is no hint in either the text or legislative history of OBRA 86 that Congress intended to restrict or rescind jurisdiction for collateral statutory and constitutional challenges. Thus, under the analysis in *Lindahl*, the 1986 amendments do not bar the Council's statutory and constitutional claims.

The Secretary's attempt to paint the Seventh Circuit's analysis of *Michigan Academy* as an aberration also is belied by numerous lower court opinions that have correctly reached the same conclusion as the opinion by Judge Easterbrook. See, e.g., *Vermont Assembly of Home Health Agencies, Inc. v. Shalala*, 18 F. Supp.2d 355, 362 (D. Vt. 1998) (even though the statutory scheme has been altered, this Circuit still recognizes that courts have subject matter jurisdiction over a challenge to a rule of general applicability); *Abbott Radiology Associates v. Sullivan*, 801 F. Supp. 1012, 1017-1018 (W.D.N.Y. 1992) ("the 1986 amendments did not displace the reasoning in *Michigan Academy*, and courts have explicitly acknowledged *Michigan Academy*'s continuing vitality."); *Abbey v. Sullivan*, 788 F. Supp. 165, 168 n.2 (S.D.N.Y. 1992) ("Contrary to defendant's assertions, the 1986 amendments to Medicare Part B do not render *Michigan Academy* a 'dead letter.'") aff'd, 978 F.2d 37 (CA2 1992); *Griffith v. Bowen*, 678 F. Supp. 942, 945 (D. Mass 1988) (there is no tension between *Michigan Academy* and the 1986 amendments). See also *United States, Qui Tam Body v. Blue Cross and Blue Shield of Alabama*, 156 F.3d 1098 (CA11 1998) (following *Michigan Academy* without suggesting that

the 1986 amendments affected its holding).

The circuit court decisions, which the Secretary cites (Pet. Brief 36-37) in arguing that *Michigan Academy* no longer is good law, did not involve collateral statutory or constitutional challenges. The conclusions in those cases that the 1986 amendments gave administrative review for the individual benefits claims at issue do not support the conclusion that jurisdiction is eliminated for collateral statutory and constitutional claims. See *National Kidney Patients Ass'n v. Sullivan*, 958 F.2d 1127 (CA DC 1992), cert. denied, 506 U.S. 1049 (1993) (the plaintiffs challenge a decision to change the level of benefits awarded under a program for dialysis patients; no statutory or facial constitutional challenge asserted); *American Academy of Dermatology v. Dept. of Health and Human Services*, 118 F.3d 1495, 1499 (CA 11 1997) (court determined that the case was really a "claim for benefits" under the Medicare Act which implicated section 405(g)); *Martin v. Shalala*, 63 F.3d 497, 503 (CA 7 1995) (involved a claim for benefits and not systemic statutory and constitutional challenges); *Farkas v. Blue Cross and Blue Shield of Michigan*, 24 F.3d 853, 854 (CA 6 1994) (plaintiff challenged a decision by an insurance carrier to place him under "Medicare Prepayment Utilization Review"; case did not involve a broad statutory or constitutional challenge); *Abbey v. Sullivan*, 978 F.2d 37, 41-42 (CA 2 1992) (concerned claims for medical benefits and the procedure followed on appeal from a specific benefit decision).

Because the Secretary has failed to establish any error in the Seventh Circuit's decision and because *Michigan Academy* remains good law, this Court should affirm the Seventh Circuit's judgment.

B. *McNary* Also Compels Affirmance of the Decision Below.

This case also is closely analogous to *McNary v. Haitian Refugee Center*, 498 U.S. 479 (1991). There, this Court analyzed section 210(e)(1) of the amended Immigration and

Naturalization Act and determined that the words "of a determination respecting an application" and "a determination" regarding SAW status described "a single act rather than a group of decisions or a practice or procedure employed in making decisions." 498 U.S. at 492. This Court concluded that such language described "the process of direct review of individual denials of SAW status, rather than . . . general collateral challenges to unconstitutional practices and policies used by the agency in processing applications. *Id.* (emphasis added); accord *Reno v. Catholic Social Services*, 506 U.S. 43, 56 (1993) (following *McNary*, concluding that "a determination respecting an application" precludes review of denials of individual applications, and rejecting argument that it precludes challenges to the legality of a regulation).

Significantly, this Court affirmed jurisdiction in *McNary* even though some judicial review ostensibly existed under IRCA. Under the administrative review mechanism in *McNary*, an individual SAW claimant could appeal to a circuit court. See 8 U.S.C. § 1160(e)(3). The review provided by section 1160(e)(3), however, was so limited that without section 1331 jurisdiction "the respondents would not as a practical matter be able to obtain meaningful judicial review. . . ." *McNary*, 498 U.S. at 496. This conclusion thus forecloses the Secretary's argument that *Michigan Academy* was limited to its facts, wherein no review was available for challenges under Part B of Medicare. *McNary* in fact expanded the holding of *Michigan Academy* to encompass instances where limited judicial review exists, but would not adequately address statutory and constitutional claims at issue. *McNary*'s holding is completely consistent with section 703 of the APA which allows judicial review in the "absence or inadequacy" of a special statutory review proceeding.

III. THE SECRETARY'S POLICY ARGUMENTS ARE BETTER DIRECTED TO CONGRESS THAN THIS COURT.

The Secretary argues that it is "fair and sensible" to

require exhaustion for this case. Pet. Brief 22. This is a policy argument better directed to Congress. Before this Court, this case only "concern[s] the construction of existing statutes. The relevant question is not whether, as an abstract matter, the rule advocated by petitioners accords with good policy. . . . Courts are not authorized to rewrite a statute because they deem its effects susceptible of improvement." *Badaraco v. Commissioner of Internal Revenue*, 464 U.S. 386, 398 (1984); see also *TVA v. Hill*, 437 U.S. 153, 194-95 (1978) ("Our individual appraisal of the wisdom or unwisdom of a particular course selected by the Congress is to be put aside in the process of interpreting a statute. . . . We do not sit as a committee of review, nor are we vested with the power of veto.")

Even if the Secretary's policy arguments were somehow relevant to this statutory construction case, they are unpersuasive because the traditional justifications for exhaustion do not apply here. The Secretary has failed to assert any "agency expertise" for the issues raised in the Amended Complaint. "Nor is there any reason to believe that the [Secretary] has any special expertise in assessing the validity of [her] regulations . . ." *Traynor*, 485 U.S. at 544.

The Secretary argues that "challenges [should] be brought in the context of a specific enforcement action." Pet. Brief 22. This argument is undermined by the federal declaratory judgment statute itself, a primary purpose of which was to enable parties to challenge the validity of statutes and avoid the "waste and destruction" that comes from having to violate a statute to test its validity. S. Rep. No. 1005, 73 Cong., 2d. Sess., at 2-3 (1934). See also Schwartz, *Administrative Law* 537 (2d ed. 1984) ("In federal administrative law, the injunction and/or declaratory judgment has become the general-utility remedy by which the legality of an administrative act may be determined . . ."). Furthermore, in enacting the APA, both houses of Congress expressed an intent that pre-enforcement declaratory judgment actions may continue to be used to test the validity of statutes. H.R. Rep. No. 1980, 79th Cong., 2d. Sess., at 42 (1946); accord S. Rep. No. 752, 79th Cong., 1st Sess., at

26 (1945) (declaratory judgment procedure may be operative before administrative review is available). This expression of congressional intent defeats the Secretary's argument that claims must be brought in specific enforcement actions. This Court has recognized that the "legislative material elucidating that seminal act manifests a congressional intention that it cover a broad spectrum of administrative actions." *Abbott Laboratories*, 387 U.S. at 140.

Moreover, the Secretary fails to offer any evidence of congressional intent that a regulatory challenge like this cannot be brought in a representational setting. As the Seventh Circuit stated, "[i]f some nursing homes may litigate on their own, they may litigate through their trade association; we don't see why the fact that other members of the Council have potential Medicare claims should cut off associational representation and compel independent litigation." Pet. App. 8a.

This is not a situation in which consideration of the underlying legal issues would necessarily be facilitated if they were raised in the context of a specific attempt to enforce the regulations. *Gardner v. Toilet Goods Ass'n*, 387 U.S. 158, 165-66 (1967). Exhaustion would be futile because the only issues in this type of case cannot be raised in an administrative hearing, there will be no factual findings made, and no agency expertise to apply. It is simply implausible that Congress intended such futility and delay. The Council has asserted systemic, facial challenges, not challenges to the regulations "as applied" to a single nursing facility. For the Council's type of claims, a court is not reviewing factual and discretionary decisions of an administrative law judge or Appeals Board in a run-of-the-mill benefits determination. *Oestreich v. Selective Service Bd.*, 393 U.S. 233, 241 (Harlan, J., concurring) (a claim of facial invalidity of a procedure does not require a court to review the factual and discretionary decisions inherent in the classification or processing of registrants). "Where the constitutionality of a statute or other act is challenged as facially invalid, the administrative process is unlikely to contribute anything to the resolution of

the challenge." Schwartz, *supra*, 518.

The Secretary also contends that exhaustion prevents "overly casual . . . judicial intervention in an administrative process." Pet. Brief 22 (quoting *Ringer* and *Salfi*). The language quoted from *Ringer* contains the phrase (omitted by the Secretary) "overly casual or premature judicial intervention in an administrative system." *Ringer*, 466 U.S. at 627 (emphasis added); see also *Salfi*, 422 U.S. at 749 (exhaustion generally required "as a matter of preventing premature interference with agency processes . . ." (emphasis added)). There is nothing "premature or overly casual" about a federal court considering systemic statutory or constitutional challenges to regulations already being applied. This becomes clearer when considering the dual roles of administrative agencies.

"[A]dministrative agencies typically have both legislative and judicial powers concentrated in them. They have authority to issue rules and regulations that have the force of law (power that is legislative in nature) and authority to decide cases (power judicial in nature)." Schwartz, *supra*, 10. In the exercise of the legislative function (issuing rules and regulations) administrative agencies pose the greatest danger for infringing the rights of the greatest number. If an agency's "rules of the game" are bad, constitutional violations proliferate. Congress understood this danger and therefore established the notice-and-comment requirements of the APA as one check on the legislative activities of agencies. See 5 U.S.C. § 553; see also H.R. Rep. No. 1980, 79th Cong., 2d. Sess., at 17 (1946) (the APA "provides quite different procedures for the 'legislative' and 'judicial' functions of administrative agencies. In the 'rule making' (that is 'legislative') function it provides that with certain exceptions agencies must publish notice and at least permit interested parties to submit their views in writing before . . . the issuance of general regulations (sec 4).").

After an agency has completed the legislative function, and rules and regulations have been established, there is nothing "premature" about a court considering their facial validity. A

facial/collateral challenge to a regulation's validity is a challenge to an agency's legislative work. Nothing is gained by waiting for the agency to perform its quasi-judicial function of deciding individual cases.

In arguing for an independent federal judiciary, Alexander Hamilton aptly stated: "From a body which had had even a partial agency in passing bad laws, we could rarely expect a disposition to temper and moderate them in application . . . [s]till less could it be expected that men who had infringed the constitution, in the character of legislators, would be disposed to repair the breach, in the character of judges." *The Federalist No. 81*, at 543-44 (Alexander Hamilton) (Jacob Cooke ed., 1961). This all the more true here, where the bureaucrats who must bear the administrative inconvenience of conferring greater due process are the ones who would be expected to "repair the breach". This Court has agreed with this view. "It is unrealistic to expect that the Secretary would consider substantial changes in the current administrative review system at the behest of a single aid recipient raising a constitutional challenge in an adjudicatory context." *Mathews*, 424 U.S. at 330. The availability of immediate judicial review is critical whenever an agency promulgates unconstitutional regulations with widespread effect.

In contrast, when an agency is performing its judicial function (deciding individual benefit cases), immediate judicial review may be inappropriate until after a final decision, just as interlocutory appeals can be inappropriate disruptions to the trial process. See Schwartz, *supra*, 503. In such situations, agency expertise and the compilation of an administrative record can serve a useful purpose prior to judicial review. *Salfi*, 422 U.S. at 765. No similar useful purpose exists where, as here, a claimant asserts broad statutory and constitutional challenges. Indeed, when the agency's unconstitutional conduct causes widespread harm, initial judicial review is beneficial.

The Secretary's argument that exhaustion "may avert the need for judicial review altogether" (Pet. Brief. 23) pertains

again to an agency's quasi-judicial role of determining individual claims. Exhaustion should never be allowed to thwart "judicial review altogether" of an agency's improper regulatory actions having widespread impact. If so, the agency has a "blank check." If an agency enacts a compliance program that violates due process, judicial review is necessary to check the proliferation of constitutional violations that will result. The Secretary's apocalyptic suggestion of "devastating consequences" from "judicial interference" is an exaggeration, and an insult to the federal judiciary. Claims of interference are no reason for federal courts to abdicate their responsibility. The judiciary -- not the Secretary -- decides whether the Secretary has exceeded her powers. "[U]nder Article III, Congress established courts to adjudicate cases and controversies as to claims of infringement of individual rights . . . by the exertion of unauthorized administrative power." *Stark v. Wickard*, 321 U.S. 288, 310 (1944). If the Secretary exceeds her powers, the federal courts are constitutionally permitted to "interfere."

Finally, the Secretary cites the distinguishable *Lujan* case in favor of her policy argument that this Court should "reduce the scope of the controversy." Pet. Brief 22. In *Lujan*, the claims were much broader than the Council's here. The National Wildlife Federation asserted an amorphous challenge to the "entirety" of the "land withdrawal review program." *Lujan v. National Wildlife Federation*, 497 U.S. 871, 890 (1990). That program encompassed "1250 or so individual classification terminations and withdrawal revocations." *Id.* The Council's claims are much more focused than in *Lujan*. Moreover, the Court in *Lujan* expressly recognized that regulations with "across the board"-applicability can be challenged. *Lujan*, 497 U.S. at 890-91, n.2 ("If there is in fact some specific order or regulation, applying some particular measure across the board . . . it can of course be challenged under the APA . . ."). Thus, *Lujan* does not undermine the Seventh Circuit's judgment below.

CONCLUSION

The plain language of the statute, its structure and purpose, and its legislative history, all confirm that Congress did not intend to preclude initial judicial review of the Council's constitutional and statutory challenges to the Secretary's regulations and enforcement practices. For these reasons, this Court should affirm the judgment of court of appeals.

Respectfully submitted,

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APPENDIX
STATUTORY PROVISIONS

1. Sections 405(a) and (b) of Title 42, United States Code, provide:

§ 405. Evidence, procedure, and certification for payments

(a) Rules and regulations; procedures

The Secretary shall have full power and authority to make rules and regulations and to establish procedures, not inconsistent with the provisions of this subchapter, which are necessary or appropriate to carry out such provisions, and shall adopt reasonable and proper rules and regulations to regulate and provide for the nature and extent of the proofs and evidence and the method of taking and furnishing the same in order to establish the right to benefits hereunder.

(b) Administrative determination of entitlement to benefits; findings of fact; hearings; investigations; evidentiary hearings in reconsiderations of disability benefit terminations; subsequent applications

(1) The Secretary is directed to make findings of fact, and decisions as to the rights of any individual applying for a payment under this subchapter. Any such decision by the Secretary which involves a determination of disability and which is in whole or in part unfavorable to such individual shall contain a statement of the case, in understandable language, setting forth a discussion of the evidence, and stating the Secretary's determination and the reason or reasons upon which it is based. Upon request by any such individual or upon request by a wife, divorced wife, widow, surviving divorced wife, surviving divorced mother, surviving divorced father, husband, divorced husband, widower, surviving divorced husband, child, or parent who makes a showing in writing that his or her rights may be prejudiced by any decision the Secretary has rendered, he shall give such applicant and such other individual reasonable notice and opportunity for a hearing with respect to such decision, and, if a

hearing is held, shall, on the basis of evidence adduced at the hearing, affirm, modify, or reverse his findings of fact and such decision. Any such request with respect to such a decision must be filed within sixty days after notice of such decision is received by the individual making such request. The Secretary is further authorized, on his own motion, to hold such hearings and to conduct such investigations and other proceedings as he may deem necessary or proper for the administration of this subchapter. In the course of any hearing, investigation, or other proceeding, he may administer oaths and affirmations, examine witnesses, and receive evidence. Evidence may be received at any hearing before the Secretary even though inadmissible under rules of evidence applicable to court procedure.

(2) In any case where --

- (A) an individual is a recipient of disability insurance benefits, or of child's, widow's, or widower's insurance benefits based on disability,
- (B) the physical or mental impairment on the basis of which such benefits are payable is found to have ceased, not to have existed, or to no longer be disabling, and
- (C) as a consequence of the finding described in subparagraph (B), such individual is determined by the Secretary not to be entitled to such benefits, any reconsideration of the finding described in subparagraph (B), in connection with a reconsideration by the Secretary (before any hearing under paragraph (1) on the issue of such entitlement) of his determination described in subparagraph (C), shall be made only after opportunity for an evidentiary hearing, with regard to the finding described in subparagraph (B), which is reasonably accessible to such individual. Any reconsideration of a finding described in subparagraph (B) may be made either by the State agency or the Secretary where the finding was originally made by the State agency, and shall be made by the Secretary

where the finding was originally made by the Secretary. In the case of a reconsideration by a State agency of a finding described in subparagraph (B) which was originally made by such State agency, the evidentiary hearing shall be held by an adjudicatory unit of the State agency other than the unit that made the finding described in subparagraph (B). In the case of a reconsideration by the Secretary of a finding described in subparagraph (B) which was originally made by the Secretary, the evidentiary hearing shall be held by a person other than the person or persons who made the finding described in subparagraph (B).

- (3) (A) A failure to timely request review of an initial adverse determination with respect to an application for any benefit under this subchapter or an adverse determination on reconsideration of such an initial determination shall not serve as a basis for denial of a subsequent application for any benefit under this subchapter if the applicant demonstrates that the applicant, or any other individual referred to in paragraph (1), failed to so request such a review acting in good faith reliance upon incorrect, incomplete, or misleading information, relating to the consequences of reapplying for benefits in lieu of seeking review of an adverse determination, provided by any officer or employee of the Social Security Administration or any State agency acting under section 421 of this title.
- (B) In any notice of an adverse determination with respect to which a review may be requested under paragraph (1), the Secretary shall describe in clear and specific language the effect on possible entitlement to benefits under this subchapter of choosing to reapply in lieu of requesting review of the determination.

42 U.S.C.A. 405(a) and (b) (West 1991).

2. Section 405(g) of Title 42, United States Code, provides:

(g) Judicial review

Any individual, after any final decision of the Secretary made after a hearing to which he was a party, irrespective of the amount in controversy, may obtain a review of such decision by a civil action commenced within sixty days after the mailing to him of notice of such decision or within such further time as the Secretary may allow. Such action shall be brought in the district court of the United States for the judicial district in which the plaintiff resides, or has his principal place of business, or, if he does not reside or have his principal place of business within any such judicial district, in the United States District Court for the District of Columbia. As part of his answer the Secretary shall file a certified copy of the transcript of the record including the evidence upon which the findings and decision complained of are based. The court shall have power to enter, upon the pleadings and transcript of the record, a judgment affirming, modifying, or reversing the decision of the Secretary, with or without remanding the cause for a rehearing. The findings of the Secretary as to any fact, if supported by substantial evidence, shall be conclusive, and where a claim has been denied by the Secretary or a decision is rendered under subsection (b) of this section which is adverse to an individual who was a party to the hearing before the Secretary, because of failure of the claimant or such individual to submit proof in conformity with any regulation prescribed under subsection (a) of this section, the court shall review only the question of conformity with such regulations and the validity of such regulations. The court may, on motion of the Secretary made for good cause shown before he files his answer, remand the case to the Secretary for further action by the Secretary, and it may at any time order additional evidence to be taken before the Secretary, but only upon a showing that there is new evidence which is material and that there is good cause for the failure to incorporate such evidence into the record in a prior proceeding; and the Secretary shall, after the case is remanded, and after hearing such additional evidence if so ordered, modify or affirm his findings of fact or his decision, or both, and shall

file with the court any such additional and modified findings of fact and decision, and a transcript of the additional record and testimony upon which his action in modifying or affirming was based. Such additional or modified findings of fact and decision shall be reviewable only to the extent provided for review of the original findings of fact and decision. The judgment of the court shall be final except that it shall be subject to review in the same manner as a judgment in other civil actions. Any action instituted in accordance with this subsection shall survive notwithstanding any change in the person occupying the office of Secretary or any vacancy in such office.

42 U.S.C.A. 405(g) (West 1991)

3. Sections 1395ff(a) and (b) of Title 42, United States Code, provide:

§ 1395ff. Determinations of Secretary

(a) Entitlement to and amount of benefits

The determination of whether an individual is entitled to benefits under part A or part B of this subchapter, and the determination of the amount of benefits under part A or part B of this subchapter, and any other determination with respect to a claim for benefits under part A of this subchapter or a claim for benefits with respect to home health services under part B of this subchapter shall be made by the Secretary in accordance with regulations prescribed by him.

(b) Appeal by individuals; provider representation of beneficiaries

(1) Any individual dissatisfied with any determination under subsection (a) of this section as to —

(A) whether he meets the conditions of section 426 or section 426a of this title, or

(B) whether he is eligible to enroll and has enrolled pursuant to the provisions of part B of this subchapter or section 1395i-2 of this title,

(C) the amount of benefits under part A or part B of this subchapter (including a determination where such amount is determined to be zero), or

(D) any other denial (other than under part F of subchapter XI of this chapter) of a claim for benefits under part A of this subchapter or a claim for benefits with respect to home health services under part B of this subchapter,

shall be entitled to a hearing thereon by the Secretary to the same extent as is provided in section 405(b) of this title and to judicial review of the Secretary's final decision after such hearing as is provided in section 405(g) of this title. Sections 406(a), 1302, and 1395hh of this title shall not be construed as authorizing the Secretary to prohibit an individual from being represented under this subsection by a person that furnishes or supplies the individual, directly or indirectly, with services or items solely on the basis that the person furnishes or supplies the individual with such a service or item. Any person that furnishes services or items to an individual may not represent an individual under this subsection with respect to the issue described in section 1395pp(a)(2) of this title unless the person has waived any rights for payment from the beneficiary with respect to the services or items involved in the appeal. If a person furnishes services or items to an individual and represents the individual under this subsection, the person may not impose any financial liability on such individual in connection with such representation.

(2) Notwithstanding paragraph (1)(C) and (1)(D), in the case of a claim arising -

(A) under part A of this subchapter, a hearing shall not be available to an individual under paragraph (1)(C) and (1)(D) if the amount in controversy is less than \$100 and judicial review shall not be available to

the individual under that paragraph if the amount in controversy is less than \$1,000; or

(B) under part B of this subchapter, a hearing shall not be available to an individual under paragraph (1)(C) and (1)(D) if the amount in controversy is less than \$500 and judicial review shall not be available to the individual under that paragraph if the aggregate amount in controversy is less than \$1,000.

In determining the amount in controversy, the Secretary, under regulations, shall allow two or more claims to be aggregated if the claims involve the delivery of similar or related services to the same individual or involved common issues of law and fact arising from services furnished to two or more individuals.

(3) Review of any national coverage determination under section 1395y(a)(1) of this title respecting whether or not particular type or class of items or services is covered under this subchapter shall be subject to the following limitations:

(A) Such a determination shall not be reviewed by any administrative law judge.

(B) Such a determination shall not be held unlawful or set aside on the ground that a requirement of section 553 of Title 5 or section 1395hh(b) of this title, relating to publication in the Federal Register or opportunity for public comment, was not satisfied.

(C) In any case in which a court determined that the record is incomplete or otherwise lacks adequate information to support the validity of the determination, it shall remand the matter to the Secretary for additional proceedings to supplement the record and the court may not determine that an item or service is covered except upon review of the supplemental record.

(4) A regulation or instruction which relates to a method for determining the amount of payment under part B of this

subchapter and which was initially issued before January 1, 1981, shall not be subject to judicial review.

(5) In an administrative hearing pursuant to paragraph (1), where the moving party alleges that there are no material issues of fact in dispute, the administrative law judge shall make an expedited determination as to whether any such facts are in dispute and, if not, shall determine the case expeditiously.

42 U.S.C.A. 1395ff(a) and (b) (West 1992).

4. Sections 1395cc(b) and (h) of Title 42, United States Code, provide:

§ 1395cc. Agreements with providers of service

(b) Termination or nonrenewal of agreements

(1) A provider of services may terminate an agreement with the Secretary under this section at such time and upon such notice to the Secretary and the public as may be provided in regulations, except that notice or more than six months shall not be required.

(2) The Secretary may refuse to enter into an agreement under this section or, upon such reasonable notice to the provider and the public as may be specified in regulations, may refuse to renew or may terminate such an agreement after the Secretary --

(A) has determined that the provider fails to comply substantially with the provisions of the agreement, with the provisions of this subchapter and regulations thereunder, or with a corrective action required under section 1395ww(f)(2)(B) of this title,

(B) has determined that the provider fails substantially to meet the applicable provisions of section 1395x of this title, or

(C) has excluded the provider from participation in a program under this subchapter pursuant to section 1320a-7 or section 1320a-7a of this title.

(3) A termination of an agreement or a refusal to renew an agreement under this subsection shall become effective on the same date and in the same manner as an exclusion from participation under the programs under this subchapter becomes effective under section 1320a-7(c) of this title.

* * * * *

(h) Dissatisfaction with determination of Secretary; appeal by institutions or agencies; single notice and hearing

(1) Except as provided in paragraph (2), an institution or agency dissatisfied with a determination by the Secretary that it is not a provider of services or with a determination described in subsection (b)(2) of this section shall be entitled to a hearing thereon by the Secretary (after reasonable notice) to the same extent as is provided in section 405(b) of this title, and to judicial review of the Secretary's final decision after such hearing as is provided in section 405(g) of this title, except that, in so applying such sections and in applying section 405(l) of this title thereto, any reference therein to the Commissioner of Social Security or the Social Security Administration shall be considered a reference to the Secretary or the Department of Health and Human Services, respectively.

(2) An institution or agency is not entitled to separate notice and opportunity for a hearing under both section 1320a-7 of this title and this section with respect to a determination or determinations based on the same underlying facts and issues.

42 U.S.C.A. 1395cc(b) and (h) (West 1992).

Supreme Court, U.S.

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In the Supreme Court of the United States

DONNA E. SHALALA, SECRETARY OF HEALTH AND
HUMAN SERVICES, ET AL., PETITIONERS

v.

ILLINOIS COUNCIL ON LONG TERM CARE, INC.

ON WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE SEVENTH CIRCUIT

REPLY BRIEF FOR THE PETITIONERS

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42 U.S.C. 1320a-7a(e)	16
Tit. XVIII, 42 U.S.C. 1395 et seq. (Medicare Act):	
42 U.S.C. 1395i-3h(2)(B)(ii)	16
42 U.S.C. 1395cc(b)(2)	1, 14
42 U.S.C. 1395cc(h)	3, 7, 9, 14, 15, 16, 17
42 U.S.C. 1395cc(h)(1)	1
42 U.S.C. 1395ff	11, 12
42 U.S.C. 1395ff(b)(1)	9
42 U.S.C. 1395ii	1, 11, 12
28 U.S.C. 1291	7, 8
28 U.S.C. 1331	4, 5, 7, 8, 9, 10, 12, 13, 15
42 C.F.R.:	
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In the Supreme Court of the United States**No. 98-1109****DONNA E. SHALALA, SECRETARY OF HEALTH AND
HUMAN SERVICES, ET AL., PETITIONERS***v.***ILLINOIS COUNCIL ON LONG TERM CARE, INC.*****ON WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE SEVENTH CIRCUIT*****REPLY BRIEF FOR THE PETITIONERS**

This case concerns the timing—not the availability—of judicial review. Respondent does not dispute that the Medicare Act provides comprehensive mechanisms for administrative and judicial review. Nor does respondent deny that one of those mechanisms entitles any nursing home that is “dissatisfied with a determination * * * that it is not a provider of services,” or that it does not “substantially comply” with the Secretary’s health, safety and quality-of-care regulations, to a hearing as provided in 42 U.S.C. 405(b), and to judicial review as provided in 42 U.S.C. 405(g). 42 U.S.C. 1395ee(h)(1) and (b)(2); Resp. Br. 7. Respondent argues, however, that that mechanism is not exclusive—despite Congress’s declaration that it “intended that the remedies provided by th[o]se review procedures shall be exclusive.” S. Rep. No. 404, 89th Cong., 1st Sess. Pt. 1, at 54-55 (1965).

That contention is foreclosed by 42 U.S.C. 405(h), incorporated into the Medicare Act by 42 U.S.C. 1395ii. The second sentence of Section 405(h) declares that “[n]o findings of fact or decision of the [Secretary] shall be reviewed by any person, tribunal, or governmental agency except as herein provided.” And the third sentence adds that “[n]o action * * * shall be brought under section 1331 or 1346 of title 28 to recover on any claim arising under this subchapter.”

"[T]he first two sentences of § 405(h) * * * assure that administrative exhaustion will be required," *Weinberger v. Salfi*, 422 U.S. 749, 757 (1975), while the third sentence "provides that § 405(g), to the exclusion of 28 U.S.C. § 1331, is the sole avenue for judicial review of all 'claim[s] arising under' the Medicare Act." *Heckler v. Ringer*, 466 U.S. 602, 614-615 (1984) (emphasis added). Simply put, where (as here) plaintiffs "have an adequate remedy in § 405(g) * * *[,] § 405(g) is the only avenue for judicial review," *Ringer*, 466 U.S. at 617—even if the plaintiffs challenge a rule or policy of general applicability, as in *Ringer* itself, *id.* at 613-616, 620-621, 624-626, and in *Salfi* as well, see Gov't Br. 34-35.

A. 1. Respondent and its amici argue that Section 405(h) applies only to "individual claims for benefits." See Resp. Br. 15, 16, 17, 21, 25. See also Am. Hosp. Ass'n (AHA) Br. 9, 12, 18; Am. Health Care Ass'n (AHCA) Br. 8. To the extent respondent and its amici suggest that Section 405(h) applies only to claims for monetary payments, this Court has already rejected that contention. In *Ringer*, the plaintiffs and the dissent contended that Section 405(h) "precludes only actions" in "which the claimant seeks payment of benefits"; it does not extend, they argued, to suits (like *Ringer*) that challenge generally applicable policies and seek only declaratory and injunctive relief. See 466 U.S. at 635 (dissenting opinion). They, like respondent, also sought to distinguish this Court's decision in *Salfi* as a benefits case. *Ibid.* This Court, however, rejected those arguments. "[T]here is no indication in *Salfi*," the Court explained, "that our holding in any way depended on the fact that the claimants there sought an award of benefits." 466 U.S. at 623. "Furthermore," the Court continued, "today we explicitly hold that our conclusion that the claims of [the respondents] are barred by § 405(h) is in no way affected by the fact that those respondents did not seek an award of benefits." *Ibid.*

Moreover, as we have explained (Gov't Br. 39-42), respondent's proposal to limit Section 405(h)'s preclusive scope to "amount," "benefits," or "reimbursement" claims has no

basis in the text of Section 405(h). The court of appeals suggested (Pet. App. 6a) that such a limit might be found in Section 405(h)'s third sentence, which bars federal-question jurisdiction over suits "to recover" on a claim arising under the Medicare Act. That argument is not only inconsistent with *Ringer*, but also incorrect as a textual matter. As we have pointed out (and respondent and its amici do not dispute), the word "recover" in legal contexts has never been limited to monetary recoveries. Gov't Br. 39. Moreover, the attempt to limit Section 405(h)'s preclusive effect to suits for benefits or payments cannot be reconciled with the fact that Congress expressly incorporated Section 405(h) into numerous Medicare provisions that do not involve the adjudication of claims for payments—including provisions that, like 42 U.S.C. 1395cc(h) here, deal with the imposition of remedies for noncompliance. See Gov't Br. 39-40 & n.21. Nor can it be reconciled with the statutory structure, as construing Section 405(h) to reach only benefits determinations would make the third sentence of Section 405(h) superfluous in light of the second. See p. 5, *infra*; Gov't Br. 40.¹

Although the foregoing arguments appear in our opening brief, respondent and its amici make no attempt to answer them. In fact, notwithstanding their repeated use of phrases like "benefits claims" and "amount determinations," they ultimately concede that 42 U.S.C. 405(h)'s preclusive scope extends beyond suits seeking monetary payments. Resp. Br. 18, 19, 20 (conceding that Section 405(h)'s preclusion extends to non-monetary "provider status" claims, i.e., suits challenging the termination of providers from the program);²

¹ In any event, respondent's suit—which seeks invalidation of regulations that might render its members ineligible to participate in (and therefore to receive payments under) Medicare, and seeks an injunction to prohibit "any ban on payment as a remedy for any deficiency," J.A. 52—is inextricably intertwined with payment claims. See Gov't Br. 34-35, 41-42.

² Respondent relies (Br. 20-21) on the fact that the 1965 legislative history, when stating that the statutory review procedures are exclusive, mentions only benefits determinations and "determinations regarding * * * eligibility to participate in the program." In 1965, however, those

Am. Ass'n of Homes & Servs. for the Aging (AAHSA) Br. 30 ("the issue is not whether payment of an 'amount' of money is at stake").

2. Respondent and its amici also argue that Section 405(h) is preclusive only with respect "to *individual* claims * * * for which there is an administrative hearing and a final decision." Resp. Br. 16, 19, 20, 29 (emphasis added). According to them, Section 405(h) distinguishes "between challenges to individualized determinations, which must be brought through established administrative channels," and "broad-based" pre-enforcement "challenges to the Secretary's rules and regulations governing such determinations, which may be brought directly in district court." AMA Br. 5-6; see Resp. Br. 29 (distinguishing between "statutory or constitutional challenges to a regulation or policy" and "an individual claim of entitlement").

That proposed distinction likewise has no textual basis. Section 405(h)'s second sentence does channel review of individual claims through special statutory review mechanisms. It declares that "[n]o * * * decision of the [Secretary] shall be reviewed * * * except as herein provided," 42 U.S.C. 405(h), and "decisions" of the Secretary are generally individualized determinations, see *Bowen v. Michigan Academy*, 476 U.S. 667, 679 n.8 (1986). But it would be inconsistent with the reasons for that exhaustion requirement, and with the very existence of a special statutory review procedure, to permit a party to separate out one legal issue that may bear on an administrative adjudication and present that issue in a separate anticipatory suit. In any event, the third sentence of Section 405(h) declares that "no action * * * to recover . . . any claim arising under" the Medicare Act shall be brought under Section 1331. Nothing

were the only categories that existed; terminating a provider's participation was the *only* remedy the Secretary could impose for non-compliance. Gov't Br. 7. It follows that the statutory mechanism for judicial review is exclusive with respect to the additional remedies Congress authorized in 1986 as well.

in that "sweeping and direct" language "limit[s]" its "reach * * * to decisions of the Secretary" or other individualized or fact-based claims. *Salfi*, 422 U.S. at 762. To the contrary, by its plain terms, the third sentence of Section 405(h) precludes district courts from exercising federal-question jurisdiction over "any claim" arising under the Medicare Act, whether it is characterized as "individual" or as a broad-based challenge to regulations, policies, or a provision of the Act. Moreover, because Section 405(h)'s second sentence precludes review of individual determinations ("decisions" of the Secretary) except through the special review mechanisms in the Act, respondent's "treatment of the third sentence of § 405(h) not only ignore[s] that [third] sentence's plain language, but also relegate[s] it to a function which is already performed by other statutory provisions." *Id.* at 758-750 & n.6.

For similar reasons, respondent (Br. 30) and its amici (AHA Br. 17-19; AAHSA Br. 30; AMA Br. 17-19) err in relying on *McNary v. Haitian Refugee Center, Inc.*, 498 U.S. 479 (1991), *Reno v. Catholic Social Services, Inc.*, 509 U.S. 43 (1993), *Johnson v. Robison*, 415 U.S. 361 (1974), and *Traynor v. Turnage*, 485 U.S. 535 (1988), to support their argument that Section 405(h) distinguishes between individual claims and more generalized challenges to rules and regulations. None of the statutes in those cases contained a sweeping preclusion provision comparable to the third sentence of Section 405(h).³ And in each of those cases, this Court relied on the fact that, absent review under 28 U.S.C. 1331, there would have been no mechanism for judicial review of sub-

³ In *Robison*, 415 U.S. at 367, and *Traynor*, 485 U.S. at 541, the statute barred review of "decisions of the Administrator," and in *McNary* and *Catholic Social Services*, the statute barred "judicial review of a determination respecting an application for adjustment of status," 498 U.S. at 491; 509 U.S. 53, 60. Indeed, in *McNary*, the Court emphasized that the "critical words" of the provision there referred "only to review 'of a determination respecting an application'—a 'single act' respecting an 'individual application'—and did not extend to more general challenges to "a group of decisions or a practice or procedure." 498 U.S. at 491-492.

stantial constitutional claims. *Robison*, 415 U.S. at 366-367, 373-374; *Traynor*, 485 U.S. at 542-544; *McNary*, 498 U.S. at 484, 486; *Catholic Soc. Servs.*, 509 U.S. at 63-65.

It was on those very grounds that this Court in *Salfi* distinguished *Robison* and refused to import into Section 405(h) a distinction between individualized claims and broad-based constitutional challenges to the Act itself. Whereas the statute in *Robison* precluded review only of a “decision of the administrator,” the Court explained, “[t]he language of § 405(h) is quite different. Its reach is not limited to decisions of the Secretary * * *. Rather, it extends to any ‘action’ seeking ‘to recover on any * * * claim’” arising under the Act. 422 U.S. at 761-762. Moreover, the Court explained, in *Robison* “absolutely no judicial consideration of the issue would be available” if the statute were read as precluding the suit. *Id.* at 762. Here and in *Salfi*, by contrast, Section 405(h) does not “preclude constitutional” challenges, but “simply require[s] that [such challenges] be brought under the jurisdictional grants contained in the” Act itself, “and thus in conformity” with all other “claims arising under the Act.” 422 U.S. at 762; Gov’t Br. 44-46, 47-48.⁴

This Court’s cases establish that a claim “arises under” the Social Security Act within the meaning of Section 405(h)—and review under 28 U.S.C. 1331 is therefore precluded in favor of review through 42 U.S.C. 405(g)—if the Act “provides both the standing and the substantive basis for the presentation” of the plaintiff’s contentions. *Salfi*, 422 U.S. at 760-761; *Ringer*, 466 U.S. at 615; *Mathews v. Eldridge*, 424 U.S. 319, 327 (1976). Those cases draw no distinction between claims turning on specific facts and legal claims of

⁴ Respondent seems to argue (Br. 24) that Section 405(g) does not permit judicial review of regulations except those relating to the claimant’s “burden of proof.” That assertion is incorrect. See, e.g., *Califano v. Yamasaki*, 442 U.S. 682 (1979) (reviewing, under 42 U.S.C. 405(g), the validity of regulations providing that hearings are available only after an initial “recoupment” determination); *Sullivan v. Everhart*, 494 U.S. 83 (1990) (reviewing “netting” regulations under 42 U.S.C. 405(g)).

more systemic import. Indeed, the plaintiffs in *Salfi* represented a class of plaintiffs and sought broad-based relief with respect to general practices. They requested and obtained from the district court declaratory relief and a nationwide injunction against statutory duration-of-relationship requirements alleged to be unconstitutional. 422 U.S. at 754-755. This Court nonetheless held that Section 405(h) precluded them from bringing their challenge under 28 U.S.C. 1331, in circumvention of 42 U.S.C. 405(g). 422 U.S. at 765.⁵

Nor can the distinction proposed by respondent and amici be defended under the theory that “collateral” claims are exempted from 42 U.S.C. 405(h)’s preclusive scope. Resp. Br. 29-30; AMA Br. 24; AAHSA Br. 10; AHCA Br. 10-11. Even if we assume, *arguendo*, that respondent’s claims are “collateral” to the merits of enforcement actions that might be brought against its members, this Court has specifically held that “[t]he only avenue for judicial review” of collateral claims “is 42 U.S.C. 405(g).” *Eldridge*, 424 U.S. at 327, 330-332; *Bowen v. City of New York*, 476 U.S. 467, 483-486 (1986).⁶

⁵ Respondent suggests that because 42 U.S.C. 405(b)—which, as incorporated into 42 U.S.C. 1395cc(h), provides a right to an administrative hearing—is focused on individualized fact-bound disputes, Section 405(h) should be so read as well. But Congress chose to provide for administrative and judicial review under the special statutory review procedures only in connection with claims arising out of specific enforcement actions precisely to ensure that adjudication would take place in a concrete, factual setting; permitting abstract pre-enforcement challenges in district court outside the special statutory mechanism would defeat that purpose. The text of Section 405(h)’s third sentence, its legislative history, and *Ringer* and *Salfi* are all, in any event, directly contrary to respondent’s position. See pp. 2-5, *supra*. Respondent and its amici also argue that 42 U.S.C. 405(b) provides for administrative review only with respect to monetary issues (i.e., benefits claims). See Resp. Br. 15-16; AHCA Br. 7. But the review provided by Section 405(b), as incorporated *mutatis mutandis* into the particular aspect of the Medicare program at issue here, cannot be limited to monetary claims, since Section 1395cc(h) gives providers a right to a Section 405(b) hearing on matters that do not involve requests for payment, as respondent concedes (Br. 16, 20).

⁶ *Eldridge* and *City of New York* held that collateral claims could be raised through Section 405(g) itself without complete exhaustion because

Finally, the “individual” claim gloss that respondent seeks to place on Section 405(h)’s plain language is implausible. Under respondent’s view, providers with the least need for immediate judicial review—those that do not face imminent enforcement proceedings and instead assert only abstract facial challenges—would have immediate access to the courts, while a provider subjected to an enforcement action would have to exhaust administrative remedies. See Gov’t Br. 43. Respondent’s construction also defeats the purposes of the statutory design. By requiring claims to arise in the concrete factual setting of a specific enforcement action, the Act ensures that controversies are of manageable proportions, that constitutional issues can be avoided if possible, and that judicial review does not prematurely or unduly interfere with this important federal program. It is precisely such an unmanageable broadside attack—a suit that demands constitutional adjudication in the abstract and that requests a broad injunction against the use of the very remedies Congress found to be essential to enforcement of Medicare’s health, safety, and quality-of-care regulations—that respondent has brought here. See Gov’t Br. 26-28.⁷

Section 405(g)’s requirement of a “final” decision—like the “final decision” requirement of 28 U.S.C. 1291—permits immediate review of collateral legal issues in exceptional circumstances once a claim has been presented to the Secretary. See Gov’t Br. 46-47 n.26; cf. *Cohen v. Beneficial Indus. Loan Corp.*, 337 U.S. 541 (1949). In *Eldridge* and *City of New York*, moreover, the Court held that a collateral issue can be raised under 42 U.S.C. 405(g) without complete exhaustion only if (1) a claim has been presented to the Secretary, and (2) relief on the collateral issue could not be afforded after exhaustion. 424 U.S. at 331-332; 476 U.S. at 483. If respondent were correct that claims can be brought under 28 U.S.C. 1331 merely because they are in some sense “collateral”—without presentation to the Secretary and without a showing of irreparable injury—then those requirements would be superfluous.

⁷ Respondent’s argument (Br. 21-22) that the Declaratory Judgment Act, 28 U.S.C. 2201, and the Administrative Procedure Act, 5 U.S.C. 702-704, authorize suit under 28 U.S.C. 1331 is also unavailing. The Declaratory Judgment Act creates a remedy; it is not an independent jurisdictional grant. *Skelly Oil Co. v. Phillips Petroleum Co.*, 339 U.S. 667, 671

B. In the end, respondent and its amici rely primarily not on the text of Section 405(h) but rather on *Michigan Academy*, which they construe as creating an across-the-board distinction between “amount claims,” to which Section 405(h) concededly applies, and “methodology claims,” to which it allegedly does not. See Resp. Br. 33-40; AMA Br. 12-21, 24-30. But they do not dispute that *Michigan Academy* expressly declined to provide a generalized construction of Section 405(h), see 476 U.S. at 680, or that the two alternative constructions it did identify both would bar respondent’s extra-statutory pre-enforcement suit. Gov’t Br. 38. Respondent and amici likewise do not dispute that the Court in *Michigan Academy* derived its “amount/methodology” distinction from the language of 42 U.S.C. 1395ff(b)(1), a provision that is not applicable here, and that the provision that is applicable in this case, 42 U.S.C. 1395cc(h), does not support that distinction and has nothing to do with “amount” claims in any event. Gov’t Br. 33.

More fundamentally, respondent and its amici do not dispute that *Michigan Academy* relied heavily on the presumption that Congress intends judicial review to be available in some manner—and the canon that statutes should be construed to avoid serious constitutional questions—because, absent review under 28 U.S.C. 1331, the Secretary’s interpretation of Part B payment obligations would have been absolutely unreviewable. Gov’t Br. 31-32. Nor, finally, do

(1950). It therefore cannot create jurisdiction under 28 U.S.C. 1331 where 42 U.S.C. 405(h) withdraws it, and the Court in *Ringer* specifically rejected the contention that a declaratory judgment action can be used to circumvent the special statutory review procedure in Section 405(g). See 466 U.S. at 621-622. Likewise, the APA does not create subject-matter jurisdiction; it merely creates a cause of action. *Califano v. Sanders*, 430 U.S. 99, 106 (1977). Moreover, that cause of action is unavailable on its own terms where, as here, Congress has provided a “special statutory review proceeding relevant to the subject matter” if that mechanism is adequate. 5 U.S.C. 703; Gov’t Br. 25-26. Here, the special statutory mechanism—quite aside from being rendered exclusive by the Medicare Act itself, 42 U.S.C. 405(h)—is fully adequate. See pp. 14-20, *infra*.

they dispute that the Court relied extensively on legislative history indicating that Congress did not intend to foreclose judicial review altogether. *Id.* at 32-33. Since the question here is not the *reviewability* of the Secretary's regulations and policies but rather its *timing*, neither the rules of construction nor the legislative history on which *Michigan Academy* relied applies to this case. See *National Kidney Patients Ass'n v. Sullivan*, 958 F.2d 1127, 1133 (D.C. Cir. 1992) ("[T]he court in *Michigan Academy* was concerned not with timing, but with reviewability *vel non*."), cert. denied, 506 U.S. 1049 (1993); Gov't Br. 31-34 (additional cases).

For that reason, respondent and its amici's reliance on selective quotes from *Michigan Academy* is unavailing. Respondent, for example, relies on *Michigan Academy*'s observation that "[t]he legislative history * * * provides specific evidence of Congress' intent to foreclose review only of 'amount determinations'—*i.e.*, those 'quite minor matters,' remitted finally and exclusively to adjudication by private insurance carriers in a 'fair hearing,'" and the statement that "matters which Congress did not delegate to private carriers, such as challenges to the validity of the Secretary's instructions and regulations, are cognizable in courts of law." Resp. Br. 35-36. But again, the question here is not whether Section 405(h) "foreclose[s]" such challenges altogether. It is whether Congress, by providing for review through 42 U.S.C. 405(g), and barring recourse to alternative mechanisms through 42 U.S.C. 405(h), required challenges to rules and policies to be routed through the express statutory mechanism for administrative and judicial review.⁸ *Ringer*

⁸ Citing this Court's statement that "matters which Congress did not leave to be determined in a 'fair hearing' conducted by the carrier—including challenges to the validity of the Secretary's instructions and regulations—are not impliedly insulated from judicial review by 42 U.S.C. 1395ff," respondent also argues that *Michigan Academy* makes judicial review available under 28 U.S.C. 1331 for any issue that an ALJ would not address under 42 U.S.C. 405(b). Resp. Br. 35. That result would be flatly inconsistent with *Salfi*, where the Court held that a challenge to the constitutionality of the Act, which could not be resolved by an ALJ,

squarely held that it did. See p. 2, *supra*.⁹ Simply put, Congress paired Section 405(g) with Section 405(h) for the obvious purpose of excluding through the latter, at a minimum, those claims that could be raised under the former. Since claims like respondent's—unlike the claims at issue in *Michigan Academy* when that case was decided—can be raised under Section 405(g), Section 405(h) precludes their assertion here.

2. The amount/methodology distinction drawn by *Michigan Academy* in any event has been superseded by statute even in the specific context in which that case arose. In 1986, shortly after *Michigan Academy* was decided, Congress amended 42 U.S.C. 1395ff to provide an express mechanism by which providers can challenge Part B reimbursement determinations in court, and thereby raise their Part B "methodology" claims as well. Since then, the courts of appeals have unanimously agreed that *Michigan Academy*'s holding that "methodology" claims can be raised outside of express statutory mechanisms has been superseded. Gov't Br. 36-37.¹⁰ The legislative history of the 1986 amend-

nevertheless had to be brought under Section 405(g). See 422 U.S. at 760-764. Read in context, the sentence respondent quotes from *Michigan Academy* merely states that Congress, by omitting any special mechanism by which Part B "methodology" claims could be asserted first in an administrative forum and *then* in court, had not clearly indicated its intent to foreclose judicial review of such claims altogether. The Court was not addressing the very different question of whether, when Congress *does* provide for administrative and then judicial review, Section 405(h) renders that mechanism exclusive.

⁹ As the District of Columbia Circuit has observed, a broad construction of *Michigan Academy* like respondent's would "require a decision that *Michigan Academy* either overruled *Ringer* * * * or assumed that it was only an 'amount' case, not a methodology dispute. The latter would be a stretch, however, as *Ringer* revolved around the legality of the Secretary's policy statement expressing her *generic* approach to BCBR * * * operations." *National Kidney Patients Ass'n*, 958 F.2d at 1132.

¹⁰ The AMA (Br. 20) and respondent (Br. 38) point out that Congress did not amend 42 U.S.C. 1395ii, or 42 U.S.C. 405(h), in 1986. As the AMA recognizes (Br. 14-15), in *Michigan Academy* this Court construed the scope of 42 U.S.C. 1395ii and 405(h) in light of 42 U.S.C. 1395ff, reading

ment, which explains that it was designed to bring review of Part B claims into line with review of Part A claims, H.R. Rep. No. 727, 99th Cong., 2d Sess. 95 (1986), supports that conclusion; the courts of appeals (like this Court in *Ringer*) have long recognized that, with respect to Part A claims, the Medicare Act's special review mechanism is exclusive.¹¹

Respondent and its amici seek to bolster their argument that *Michigan Academy* has continuing vitality with respect

them as not foreclosing review when neither Section 1395ff nor any other provision of the Act provided a mechanism for review. Congress has since amended Section 1395ff to provide for judicial review of Part B claims, thereby rendering inapplicable to Part B "methodology" claims the limitation on the reach of Section 405(h) and 1395ii the Court identified in *Michigan Academy*. When Congress amends one set of provisions, the effect of related statutory provisions may be altered as well. See, e.g., *Clark v. Uebersee Finanz-Korporation*, A.G., 332 U.S. 480, 489 (1947). Respondent likewise errs in asserting (Br. 37-38) that *Michigan Academy* must still be good law because this Court has cited it for various propositions—in non-Medicare cases—since the 1986 amendment. This Court often cites a prior case for a particular principle even after the statute that case interpreted has been amended in a way that may overturn the specific result reached. See, e.g., *McKennon v. Nashville Banner Publ'g Co.*, 513 U.S. 352, 360-361 (1995) (citing *Price Waterhouse v. Hopkins*, 490 U.S. 228 (1989), even though it was superseded by statute, see *Landgraf v. USI Film Prod.*, 511 U.S. 244, 251 (1994)); *Seminole Tribe v. Florida*, 517 U.S. 44, 54 n.7, 55-56 (1996) (citing *Atascadero State Hosp. v. Scanlon*, 473 U.S. 234 (1985), even though the statute was amended in response to *Atascadero*, see *Lane v. Peña*, 518 U.S. 187, 198 (1996)).

¹¹ See *National Kidney Patients*, 958 F.2d at 1132; *St. Francis Med. Ctr. v. Shalala*, 32 F.3d 805, 812-813 (3d Cir. 1994), cert. denied, 514 U.S. 1016 (1995); *Westchester Mgm't Corp. v. HHS*, 948 F.2d 279, 282 (6th Cir. 1991), cert. denied, 504 U.S. 909 (1992). Notwithstanding those decisions, amicus AMA contends (Br. 13 & n.9, 22) that *Michigan Academy* permits both Part A and Part B "methodology" claims to be asserted under 28 U.S.C. 1331. That argument is foreclosed by *Ringer* insofar as Part A is concerned. Moreover, the AMA cites not one decision that so concludes under Part A, and never explains how the reasoning of *Michigan Academy*—which rests almost solely on the fact that review of Part B methodology claims would have been entirely unavailable absent review under 28 U.S.C. 1331, see 476 U.S. at 670-674, 678-681—could be applicable to Part A methodology claims, which could always be raised in the context of a specific reimbursement determination.

to Part B "methodology" challenges by quoting Representative Wyden's assertion that the 1986 amendment "strengthens the rights established by * * * Bowen versus Michigan Academy." Resp. Br. 38 (quoting 132 Cong. Rec. 32,978 (1986)). But that isolated statement does not support respondent's position.¹² Even though the 1986 amendment superseded *Michigan Academy*'s specific holding that Part B methodology challenges may be brought under 28 U.S.C. 1331, it strengthened the right to insist on a proper methodology by establishing a special (and exclusive) statutory mechanism by which physicians can challenge the individual reimbursement decisions in which the Secretary applies her methodology. Under *Michigan Academy*, in contrast, physicians could not challenge individual determinations, and thus could not avoid losses from even a wholly unlawful methodology except by obtaining a declaratory judgment before the Secretary actually applied that methodology.

Finally, respondent's argument that the 1986 amendment codifies the specific holding in *Michigan Academy* cannot be reconciled with the fact that identical changes were proposed in 1985, before *Michigan Academy* was decided. Nor can it be reconciled with the fact that, when those changes were proposed in 1985, Congress clearly understood that the new mechanism for review would be exclusive. Indeed, the amendment's proponents justified it by explaining that, absent the legislation, no review would be available at all.¹³

¹² Such an isolated floor statement is entitled to little weight, *Weinberger v. Rossi*, 456 U.S. 25, 35 n.15 (1982), especially where (as here) the statement was inserted into the Congressional Record after the fact, see 132 Cong. Rec. at 32,707 (1986) (explaining significance of typeface); Congressional Quarterly, *How Congress Works* 101 (3d ed. 1998). See *Gustafson v. Alloyd Co.*, 513 U.S. 561, 580 (1995).

¹³ See 131 Cong. Rec. 22,274, 22,275 (1985) (bill necessary to provide "judicial review of claims disputed by Medicare's beneficiaries," and "to guarantee * * * due process"); *id.* at 22,275 (bill necessary because "[f]or Part B beneficiaries, as well as providers, the Medicare statute and recent court decisions have effectively precluded judicial review of part B programs and claims"); *ibid.* (reform necessary because total preclusion of

C. Finally, abandoning the rationale of the court of appeals, respondent and its amici argue that the specific statutory mechanisms for review established by the Medicare Act are inadequate. But Congress, in establishing those mechanisms and rendering them exclusive, deemed them adequate under the vast Medicare program, and courts may not carve out exceptions to that statutory arrangement based on their own assessments of adequacy. In any event, respondent's and amici's complaints are without merit.

1. AAHSA asserts (Br. 16, 19) that Section 1395cc(h) provides no right to review at all except "in the limited instances where a provider has been terminated or excluded from the Medicare program, or assessed a [civil money penalty]." See also Resp. Br. 27. That assertion is incorrect. See Gov't Br. 5. Section 1395cc(h) provides for review where a provider is "dissatisfied" with a determination that the provider is "not a provider of services," such as where the Secretary decides to terminate it from Medicare, "or with a determination described in subsection (b)(2)." Subsection (b)(2) in turn describes several types of determinations, including a "determin[ation] that the provider fails to comply substantially with the provisions of [its provider agreement]," or "with the provisions of [the Medicare Act] and regulations thereunder." 42 U.S.C. 1395cc(b)(2). Section 1395cc(h) thus permits review not only when the provider is terminated or excluded from the program, but also when (because some other remedy is imposed) it is dissatisfied with a finding that it is not in substantial compliance with its provider agreement, the Act, or the Secretary's regulations.¹⁴

review is potentially unconstitutional); *id.* at 17,232, 17,244 (bill would permit judicial review of Part B claims).

¹⁴ AAHSA's contention that review is available only when a termination occurs also renders Section 1395cc(h)'s reference to "determinations described in subsection (b)(2)" mere surplusage, because Section 1395cc(h), even absent that reference, makes any decision to terminate a provider reviewable as a determination that the institution "is not a provider of services." See also Gov't Br. 5 n.4 (noting that phrase "not a provider of services" can be construed to include findings of non-

Respondent admits (Br. 7) that Section 1395cc(h) provides for administrative and judicial review of any finding of non-compliance where a remedy is imposed. See also AHA Br. 10. But it argues that review should be permitted under 28 U.S.C. 1331 because ALJs cannot rule on challenges to the Secretary's regulations and therefore would not develop a factual record, and because judicial review under 42 U.S.C. 405(g) is limited to the administrative record. See Resp. Br. 23-26; AHCA Br. 12, 15. That argument is without merit. First, facial challenges to regulations generally do not require a factual record beyond what was developed in the rulemaking proceeding, and an as applied challenge generally can be resolved on the basis of the administrative record. Second, although ALJs are bound by the Secretary's regulations and ought not rule on their validity, nothing precludes ALJs from accepting proffers of evidence relevant to such challenges in appropriate circumstances. Cf. 42 C.F.R. 498.61 (ALJ not bound by rules of evidence, including relevance). Third, district courts can "at any time" remand a case with an inadequate record and "order additional evidence to be taken." 42 U.S.C. 405(g); see *Sullivan v. Hudson*, 490 U.S. 877, 885 (1989). Fourth, it is well settled in administrative law generally that, if agency processes do not permit necessary record development for substantial constitutional claims, the district court may allow the parties to supplement the record.¹⁵ Section 405(g) should not be construed to depart from that approach where constitutional

compliance). The Secretary's construction of the hearing right provided by Section 1395cc(h) is entitled to deference. See, e.g., *Your Home Visiting Nurse Servs. v. Shalala*, 119 S. Ct. 930, 933-934 (1999).

¹⁵ *American Trucking Ass'n v. United States*, 344 U.S. 298, 320 (1953) (The "right to introduce evidence to support the [constitutional] claim * * * may be enforced in the District Court, if the Commission bars an opportunity to do so."); cf. *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 415 (1971) (under APA, "there may be independent judicial factfinding" in adjudicatory actions when "agency factfinding procedures are inadequate" and "when issues that were not before the agency are raised in a proceeding to enforce nonadjudicatory action").

claims are raised. Cf. *City of New York*, 476 U.S. at 473-474, 478 (noting district court trial on unique “secret policy” issue in suit under 42 U.S.C. 405(g)).¹⁶

Respondent complains that, because 42 U.S.C. 1395cc(h) provides for review only in the context of actual noncompliance findings, associational plaintiffs like respondent—which do not operate nursing homes and thus are not subject to noncompliance findings—cannot seek judicial review in their own right. Resp. Br. 32-33; AMA Br. 28-30. Because respondent’s standing derives from and extends no further than that of its members, and because its members have an adequate remedy under 42 U.S.C. 1395cc(h), the fact that respondent cannot sue under that provision causes it no legally cognizable injury.¹⁷ Respondent, moreover, can raise its issues in court by participating as amicus when one of its members seeks judicial review, and it can facilitate review by assuming a member’s litigation costs.

2. Respondent’s and amici’s remaining arguments are directed not at the adequacy of the *statutory* review mecha-

¹⁶ In *McNary*, relied upon by respondent (Br. 25-26; see AHCA Br. 12), the record could not be developed in district court because judicial review was directed to the courts of appeals, 498 U.S. at 497. AHCA attempts (Br. 15) to make this case more like *McNary* by noting that review of civil money penalties is directly in the court of appeals. The scope of administrative review in the context of civil money penalties, however, is broader than in other contexts, 42 C.F.R. 498.3(b)(13), 488.438(e) and (f); p. 20, *infra*, and the statutory provision governing such appeals, 42 U.S.C. 1320a-7a(e) (as incorporated by 42 U.S.C. 1395i-3h(2)(B)(ii)), provides for remands for factfinding under appropriate conditions.

¹⁷ For the same reason, respondent (Br. 33) and its amici (AAHSA Br. 2-4, 26-27) err in relying on *Nader v. Alleghany Airlines, Inc.*, 426 U.S. 290, 302 (1976), *Rosado v. Wyman*, 397 U.S. 396, 406 (1970), and *Estate of Smith v. Heckler*, 747 F.2d 583 (10th Cir. 1984). None of those cases held that an association that has no interests other than those of its members can bring suit outside of an otherwise exclusive statutory review procedure where that procedure provides the association’s members with a way to obtain judicial review. To the contrary, in those cases, the statute provided neither the members nor a relevant association with an express mechanism for seeking review; the question therefore was whether Congress intended to bar review altogether.

nisms, but rather at the Secretary’s implementation. In essence, they argue that the Secretary’s regulations restrict the scope and availability of administrative review under 42 U.S.C. 1395cc(h) in a manner that renders it inadequate as a practical matter. See Resp. Br. 26-27; AAHSA Br. 16-25; AHCA Br. 14-27. Those contentions, however, can be raised on judicial review under 42 U.S.C. 405(g), as incorporated into 42 U.S.C. 1395cc(h). See, e.g., *Eldridge, supra* (challenging regulations that did not provide a pre-deprivation hearing); *Califano v. Yamasaki*, 442 U.S. 682 (1979) (similar). And precisely those claims have been raised under 42 U.S.C. 405(g) in the context of specific enforcement actions. See, e.g., *Rafael Convalescent Hosp. v. Shalala*, No. C-97-1967 FMS, 1998 WL 196469 (N.D. Cal. Apr. 15, 1998) (due process, vagueness, and APA challenges to regulations); *Beverly Health & Rehab. Serv. v. Shalala*, No. 99-09012 (N.D. Cal. complaint filed Sept. 3, 1999) (similar). Thus, far from justifying bypass of the special statutory mechanism for administrative and judicial review, respondent’s and amici’s attack on the regulations is precisely the sort of challenge that should be raised under that mechanism.

The claims of inadequacy are, in any event, without merit. Respondent and its amici complain that the Secretary’s regulations do not provide for administrative review unless a remedy is imposed, 42 C.F.R. 498.3(b)(12), and that the Secretary ordinarily rescinds proposed remedies if a non-complying provider files a plan of correction and cures the violation within a specified period of time. According to respondent and its amici, the Secretary’s practice of requiring them to correct their violations immediately, and not providing for an appeal if, in light of the immediate correction, no remedy is imposed, “coerces” them into surrendering their right to administrative review. Resp. Br. 26-27; AAHSA Br. 17-18; AHCA Br. 17.

It is hard to see how the Secretary’s decision *not* to impose penalties on a provider in a particular instance—i.e., giving the provider a chance to correct deficiencies before

imposing remedies—could be a basis for complaint. The Secretary could impose remedies in all cases of noncompliance without providing an opportunity to correct (with the incidental effect of permitting immediate appeal of every noncompliance finding). But a practice of imposing penalties for all violations without opportunity for correction would not make nursing homes and other providers better off.

Nor do the Secretary's regulations "coerce" providers into surrendering their appeal rights. Although amici are correct that nursing homes face the possibility of termination if they fail to submit a voluntary plan of correction and correct the deficiencies, AHCA Br. 17-19; AAHSA Br. 17-18, 22, see also 42 C.F.R. 488.456(b)(ii), terminations from the program are rare and generally reserved for the most egregious recidivist institutions. HHS has informed us that, between July 1995 and June 1996, only 25 of 13,166 nursing homes were terminated. More important, providers are not penalized for preserving their appeal rights. The remedy imposed on a facility that fails to submit a plan of correction or to correct a deficiency—and appeals the deficiency—is no different than the remedy the Secretary ordinarily would impose in the first instance, upon identifying the deficiency, if the Secretary did not give the facility an intervening opportunity to correct. Facilities thus do not face termination for failing to correct or submit a plan of correction in order to preserve their appeal rights; they face termination for noncompliance, and then only if the noncompliance is sufficiently dangerous to patient health to warrant that remedy.

Amici also argue that the regulations—by not providing for appeal of deficiency findings if the deficiencies are corrected and no remedy is imposed—cause providers to suffer more severe penalties in later enforcement actions based on findings that are unreviewable. AHCA Br. 19-21; AAHSA Br. 18, 22. The very administrative decisions they cite, however, refute that contention. In *Fort Tryon Nursing Home v. HCFA*, DAB No. CR425, 1996 WL 385660 (HHS July 3, 1996), for example, the Department Appeals Board ex-

plained that, although the challenged deficiency was not subject to administrative review because no remedy had been imposed, if HCFA later "determined to impose a remedy based on the finding of a new deficiency coupled with [the provider's] past compliance record, including the finding of deficiency on which [the provider] bases its current hearing request, then [the provider] would have a right to a hearing, both as to the existence of the new deficiency and as to the existence of the deficiency which is at issue here." (Emphasis added).¹⁸

Finally, AHCA complains (Br. 23) that the agency's characterization of the scope and severity of violations, and the agency's exercise of discretion in selecting remedies, are not subject to administrative review. But it does not deny that those issues are subject to judicial review. See Gov't Br. 48-49 n.27. See also *Thunder Basin Coal Co. v. Reich*, 510 U.S. 200, 215 (1994) (review mechanism exclusive "[e]ven if" the agency would not adjudicate certain claims, if those issues would "be meaningfully addressed" on judicial review). Moreover, the factual predicates for the scope and severity characterizations are within the scope of administrative review; only review of the characterization itself, divorced from the facts underlying it, is sometimes excluded from the hearing. See, e.g., *Beverly Health & Rehab. Springhill v. HCFA*, DAB No. CR553, 1998 WL 839612 (HHS Oct.

¹⁸ Accord *Baltic Country Manor v. HCFA*, [1986-1987 Transfer Binder] Medicare & Medicaid Guide (CCH) ¶¶ 45,038, at 52,578 (Dec. 11, 1996) (to the extent HCFA bases civil money penalty amount on earlier noncompliance, provider can "contradict or make more accurate any history of noncompliance"). AAHSA also complains (Br. 17, 18) about the Secretary's general policy of imposing sanctions immediately on so-called poor-performing facilities without offering them an opportunity to correct. But the decision to proceed with enforcement actions against such facilities immediately, and to permit others to correct their mistakes without imposing a remedy, is a wholly legitimate (and essentially unreviewable) exercise of enforcement discretion. See *Heckler v. Chaney*, 470 U.S. 821, 830 (1985); cf. *Reno v. American-Arab Anti-Discrimination Committee*, 119 S. Ct. 936, 945 (1999).

27, 1998). And the characterizations of scope and severity are subject to administrative review if a successful challenge would alter the range of permissible remedies, such as where the provider claims that its performance constituted substantial compliance (in which case *no* remedy can be imposed).¹⁹ Where civil money penalties are imposed, ALJs can consider the appropriateness of the penalty amount in light of the number and nature of the violations, even if the characterization of scope and severity is not itself reviewable. 42 C.F.R. 498.3(b)(13), 488.38(e)-(f).²⁰

* * * *

For the foregoing reasons and those stated in the opening brief, the judgment of the court of appeals should be reversed.

SETH P. WAXMAN
Solicitor General

SEPTEMBER 1999

¹⁹ See 42 C.F.R. 498.3(d)(10)(ii) (barring review of characterization of "level of noncompliance"), 488.301 (defining "noncompliance" as the condition of not being in "substantial compliance").

²⁰ Amici also complain that, where deficiencies are found, the statute requires them to post the deficiencies in a public location, and the deficiencies are listed on HCFA's website, even if they are not subject to administrative review. AAHSA Br. 22; AHCA Br. 17-18. But nothing prevents providers from posting their responses as well. Moreover, if a provider truly wishes to contest the finding, it can avoid taking actions that will cause the Secretary to forbear enforcement, and challenge the finding through administrative review. Finally, if a provider believes that the Constitution or the Act requires administrative review where the only effect of the finding is informational, it can raise that claim under 42 U.S.C. 405(g). See p. 17, *supra*. Although respondent and its amici complain about administrative delay, the agency has an active process of adjudicating the most serious cases first, and claims of inordinate delay can, under appropriate circumstances, be raised under 42 U.S.C. 405(g) as well. See *Heckler v. Day*, 467 U.S. 104, 110 n.14 (1984).

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No. 98-1109

IN THE
Supreme Court of the United States

DONNA E. SHALALA, SECRETARY OF HEALTH AND
HUMAN SERVICES, *et al.*,

Petitioners

v.

ILLINOIS COUNCIL ON LONG TERM CARE, INC.

ON WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE SEVENTH CIRCUIT

**BRIEF FOR AMERICAN ASSOCIATION OF
HOMES AND SERVICES FOR THE AGING
AS AMICUS CURIAE IN SUPPORT OF
RESPONDENTS**

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57 Fed. Reg. 39278 (Aug. 28, 1992)	4
59 Fed. Reg. 56116 (Nov. 10, 1994)	4
64 Fed. Reg. 13354, 13357 (Mar. 18, 1999)	23
64 Fed. Reg. 39934, 39935 (July 23, 1999)	13, 24
HCIA, Inc. & Arthur Anderson, LLP, <i>Guide to the Nursing Home Industry</i> (1997)	5
H.R. Rep. No. 100-391(I), 100th Cong. 1st Sess. at 452, <u>reprinted in</u> 1987 U.S.C.C.A.N. 2313-1 at 2313-272.	15, 26
Cowles Research Group, <i>Nursing Home Statistical Yearbook</i> (AAHSA 1998) at 72.	5, 6
State Operations Manual ("SOM"), HCFA Pub. 7	4, 7
§7210	9
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INTEREST OF AMICUS

The American Association of Homes and Services for the Aging (AAHSA), a national nonprofit membership association, submits this brief in support of respondent with the written consent of both parties. AAHSA and its forty affiliated state associations represent over 5,000 not-for-profit facilities and organizations providing services to over 1,000,000 aging and disabled individuals. Seventy percent of AAHSA member organizations have religious sponsors. Others are sponsored by private foundations, fraternal organizations, government agencies, unions and community groups. Approximately 3,500 of AAHSA's members are nursing homes and continuing care retirement communities with skilled nursing care components, 85% of which participate in Medicaid, Medicare or in both programs.

This case involves the availability of meaningful judicial review of the system developed by the Secretary of Health and Human Services (the Secretary of HHS) to enforce nursing home compliance with Medicaid and Medicare conditions of program participation. AAHSA provided information used in developing the 1986 report of the Institute of Medicine ("IOM"), *Improving the Quality of Care in Nursing Homes (IOM Study)*, and has for over ten years provided extensive comment on proposed federal implementing rules, communicated regularly with the Health Care Financing Administration of HHS ("HCFA") and participated extensively in committees and task forces surrounding the adoption of standards and procedures designed to implement the OBRA reforms. Additionally, AAHSA participated as *amicus curiae* before the federal district court in *Michigan Ass'n of Homes and Services for the Aging, Inc. v. Shalala*, No. 95-75278 (*MAHSA v. Shalala*), and sponsored the appeal and rehearing petition filed in the Sixth Circuit in *MAHSA v. Shalala*, 127 F.3d 496 (6th Cir. 1997), "an essentially identical case" that conflicts with the decision of the Seventh Circuit below. *Illinois Council on Long Term Care, Inc. v. Shalala*, 143 F.3d 1072, 1074 (7th Cir. 1998) (Pet. App. 1a-2a).

In sum, AAHSA's members are vitally effected by the Secretary's implementation of the OBRA enforcement scheme and significantly impacted in their operations if the system is not administered in a fair, understandable and consistent fashion.

STATEMENT

A. The Genesis Of The Current Nursing Home Survey and Enforcement Standards

By adding sections 1819 and 1919 to the Social Security Act (the Act or SSA) the Omnibus Budget Reconciliation Act of 1987 (OBRA) changed the emphasis on Medicaid and Medicare program participation for long term care providers from a physical-plant and process based approach to one oriented towards resident outcomes. OBRA §§4201, 4211, 101 Stat. 1330-160 to 1330-221, codified at 42 USC 1395i-3, 1396r. See 53 Fed. Reg. 22850 (June 17, 1988). The OBRA reforms were an outgrowth both of the IOM study which was commissioned by the Secretary in 1985 and of a class action initiated in 1983 to challenge the survey and enforcement system that predated the OBRA amendments. See *In re Estate of Smith v. O'Halloran*, 557 F.Supp. 289 (D.Colo. 1983), *rev'd sub nom In re Estate of Smith v. Heckler*, 747 F.2d 583 (10th Cir. 1984) (recognizing jurisdiction and compelling adoption of rules); *on remand sub nom In re Estate of Smith v. Bowen*, 656 F.Supp. 1093 (D.Colo. 1987) (ordering publication of survey and enforcement standards as rules on remand); *In re Estate of Smith v. Bowen*, 675 F.Supp. 586 (D. Colo. 1987) (holding Secretary in technical contempt for use of Manuals to establish key survey parameters) (collectively, *Smith* litigation). *Smith* contested the Secretary's failure to adopt nationally uniform and consistently applied patient-outcome oriented conditions of Medicaid program participation and enforcement for nursing homes. Assuming plenary jurisdiction, the court in *Smith* criticized the fact that:

None of the survey forms and guidelines was published in the Rule, and no details were given concerning the criteria for assessing . . . the patients . . . [or] for determining deficiencies. As a result, there is confusion and uncertainty about the components of the . . . system.

656 F. Supp. at 1097.

The court determined that "uniform guidelines are imperative" to achieving uniform enforcement policies, that the "failure

of the Rule to include the specifics of the . . . survey system" also raises a "procedural due process concern" (*id.*), and that "[t]he refusal of the Secretary to be bound [through the rulemaking process] by specific procedures, guidelines and forms is a dereliction of his duty . . ." *Id.* at 1096. In July 1987, the Secretary published a proposed rule to "specify clear requirements in the regulations that State surveyors could follow" in order to purge the contempt citation entered in *Smith*. 52 Fed. Reg. 24752 (July 1, 1987). These rules were finalized in 1988. 53 Fed. Reg. 22850 (June 17, 1988).

The district court ultimately authorized the Secretary to supplement the rules adopted in response to its prior orders with similar but more comprehensive rules mandated by OBRA. *Id.* In 1991 HCFA adopted final regulations to implement the new substantive standards imposed by OBRA. See 56 Fed. Reg. 48826 (Sept. 26, 1991), adopting 42 C.F.R. Part 483. These established clinical outcome and quality of standard oriented standards of care which centrally require nursing homes to structure their services to "attain or maintain the highest practical mental, physical, and psychosocial well being of each resident," 42 U.S.C. 1395i-3(b)(2) [Medicare], 1396r(b)(2) [Medicaid]; 42 C.F.R. Part 483 [both]. These substantive requirement have been in effect for nearly a decade, and have not been challenged by respondent.

Under the pre-OBRA system, surveyors determined whether or not facilities were in "substantial compliance" with the standards of participation, and the only remedies for non-compliance were termination of a facility's participation or a ban on payment for new Medicare or Medicaid admissions. Facilities that regained substantial compliance were not subject to sanction. In addition to requiring new outcome-oriented participation standards, OBRA obligated the Secretary to develop a revised enforcement scheme that included an array of "intermediate sanctions" for facilities found to be out of compliance by state or federal surveyors for survey violations that do not pose immediate jeopardy to the nursing home's residents. 42 U.S.C. 1395i-3(h)(1), (2), 1396r(h)(1), (2). Among these are State-imposed plans of correction, the imposition of temporary facility management or State monitors, and civil monetary penalties (CMPs). 42 U.S.C. 1395i-3(h)(1), (2), 1396r(h)(1), (2).

Cognizant of the *Smith* litigation, Congress specifically ordered the Secretary to enact these sanctions and remedies "through regulations" and otherwise to ensure that "each State and the Secretary shall . . . reduce inconsistency in the application of survey results among surveyors." 42 U.S.C. 1395i-3(g)(1)(D), 1396r(g)(1)(D); 42 U.S.C. 1395i-3(h)(2)(B), 1396r(g), (h)(2)(b).¹ Congress imposed an October 1, 1988 deadline for the Secretary to promulgate complementary survey and enforcement regulations containing "specific criteria" and "guidelines" to govern the application of the remedies added by OBRA by State survey agencies. 42 U.S.C. 1396r(h)(2)(A), (B). Congress further specified that the Secretary's failure to timely enact enforcement rules "shall not relieve a State of the responsibility for establishing such remedies" as are required by OBRA effective October 1, 1989. Pub. L. No. 100-203, §4213, 101 Stat. 1330, codified at 42 U.S.C. 1396r(h)(2)(B).

The October 1988 deadline passed without new survey rules being promulgated, and enforcement of the revised substantive standards was channeled into the existing survey enforcement scheme. Eventually the Secretary published proposed enforcement rules in 1992, 57 Fed. Reg. 39278 (Aug. 28, 1992), and issued final regulations which became effective July 1, 1995, and are the subject of this action, 59 Fed. Reg. 56116 (Nov. 10, 1994). These rules were accompanied by the issuance of HCFA Pub. 7, State Operations Manual (SOM), Transmittals 273 and 274 (June 1995), which also are challenged by respondent.

B. Conduct of Nursing Home Surveys and Appeals Under Current Standards

1. Medicaid Versus Medicare

This case pertains predominately if not exclusively to the Medicare program compliance. Long term care under Medicare is only an adjunct of the Part A hospital benefit, and generally extends only to admissions that follow a three (3) day or longer

1. In contrast, Congress authorized the Secretary to establish "guidelines" for setting minimum standards to be incorporated in the States' Medicaid appeal procedures. 42 U.S.C. 1396r(f)(3).

hospitalization and require highly skilled nursing or rehabilitative post-hospital care by licensed professionals. 42 U.S.C. 1395d(a)(2)(A), (b)(2). In contrast, Title XIX broadly authorizes coverage of long term care for aged and impoverished individuals, and requires participating states to cover nursing facility services. 42 U.S.C. 1396d(a)(i)(4)(A), 1396a(a)(10)(A).

Nursing homes may participate in Medicaid, Medicare or both programs. Under OBRA, separate but parallel amendments were made to Titles XVIII and XIX of the Act, and the Secretary implemented regulatory standards common to both programs. 42 U.S.C. 1395i-3, 1396r; 42 C.F.R. 483.1. According to statistics derived from HCFA's Online Survey Certification and Reporting (OSCAR) database, approximately 13% of all nursing homes (2,259) participate only in Medicaid, 8% (1,448) participate only in Medicare, and 78% (13,552) are "dually certified." Cowles Research Group, *Nursing Home Statistical Yearbook* (AAHSA 1998), at 130 (Table V-1). In 1998, 1,014,534 nursing home beds were certified under Medicaid only as compared with 57,458 certified under Medicare only and 654,442 "dually certified." *Id.* at 136 (Table V-4). Approximately 71.9% of all *patient days* in nursing home facilities are covered by Medicaid, which is by far the largest single payer for long term care, whereas Medicare covers only 8% of *patient days*. HCIA, Inc. and Arthur Anderson, LLP, *Guide to the Nursing Home Industry* (1997).

2. Inconsistent Enforcement Of The Standards

A State agency typically conducts "surveys" to assess a facility's compliance with Part 483 of CFR Title 42 under the Medicaid program and serves simultaneously under agreement with the Secretary as the Medicare survey agency for facilities that are "dually certified." 42 U.S.C. 1395aa; 42 C.F.R. 488.7, 488.330.² Both the action below and *MAHSA v. Shalala* were initiated in response to indications that the survey and enforcement system implemented in 1995 was rife with confusion and was being

2. HCFA also conducts surveys to assess compliance by state-owned nursing homes, and either independently or to validate survey findings by their state counterparts regarding Medicare compliance. See 42 C.F.R. 488.7, 488.330.

administered in a manner that varied widely from one state (and region) to the next.

After the revised enforcement system was launched in Illinois in 1995, the reported rate of substantial compliance with the OBRA standards dropped precipitously from seventy percent (70%) to six percent (6%). *Illinois Council*, 143 F.3d at 1074. Within HHS Region 5, which includes Illinois, Michigan and four other states, five percent (5%) of the facilities in Wisconsin were found to provide substandard care as compared with thirty-four percent (34%) of those in Minnesota. JA 79. Other HCFA statistics before the court in *MAHSA* reflected that even though the underlying conditions of participation were unchanged, six percent (6%) of Michigan facilities were cited for providing substandard quality care (SQC) in 1994, in contrast with over sixty percent (60%) upon the implementation of the new enforcement rules and manuals. Within Region 5, 100% of facilities found out-of-compliance on a standard survey were found in substantial compliance upon resurvey, compared with 43% of facilities in Michigan. JA 83.

Similarly, HCFA State Implementation Reports introduced in *MAHSA* reflect that SQC citations ranged anywhere from three percent (3%) up to twenty-three percent (23%) among the ten (10) HHS regions. According to HCFA's calendar year 1998 data, level "G" citations — significant because they can brand facilities as "poor performers" under recent HCFA transmittals (as discussed below) — were assigned to 2.44% of providers in Oklahoma compared with 41.81% in Connecticut, 2.7% in West Virginia, and 31.28% in Tennessee. 1998 *Nursing Home Statistical Yearbook*, *supra* at Table IV-5. Citations of Level "F" deficiencies ("widespread" violations with the potential for causing more than minimum harm) ranged from .88% of facilities in Arizona up to 12.91% of all facilities in New Jersey — a fifteen fold difference.

3. Choice Of Remedy Under OBRA

Under 42 C.F.R. 488.406, eight (8) potential remedies, in addition to "termination" of the provider agreement (including six (6) that States are obligated to adopt) may be applied against a

facility found out of substantial compliance with any federal condition(s) of participation.³ Remedies are subdivided into Categories 1 through 3, with the severity of the mandatory or optional sanctions increasing by Category. 42 C.F.R. 488.408. Selection of the appropriate penalty Category derives from the combination of the "scope" and "severity" rankings assigned to the deficiencies identified by the surveyors. This determination in turn derives exclusively from the surveyors' use of a scope and severity "Grid" published in the HCFA Pub. 7 State Operations Manual (SOM), a copy of which is reproduced at JA 66.

The imposition of no remedy, or of a Category 1, 2 or 3 remedy under the Grid turns on a combination of whether the *scope* of a given deficiency is viewed as "isolated," a "pattern" or "widespread," and on the *severity* of the violation. There are four *severity* categories, including: (1) "no actual harm with a potential for minimal harm"; (2) "no actual harm with a potential for more than minimal harm that is not immediate jeopardy"; (3) "actual harm that is not immediate jeopardy"; or (4) "immediate jeopardy to resident health or safety." With the exception of a finding of "immediate jeopardy," none of the scope or severity criteria has been defined. Instead, interpretations have evolved in the field and through the periodic issuances by HCFA to State surveyors of transmittals or information in "question and answer" format, some of which have modified or reversed HCFA's previous informal guidance. See, e.g., JA 73-74. As the chief surveyor for the Michigan State agency attested in *MAHSA*, the vaguely worded, evolving, and conflicting approaches taken by HCFA in its informal development of these standards resulted in a situation where "our own people are unable to agree on the scope and severity after very intelligent, very professional discussion."

3. These include: (1) temporary management; (2) denial of payment; (3) civil monetary penalties; (4) state monitoring; (5) transfer of residents; (6) closure of the facility with transfer of residents; (7) directed plan of correction; (8) directed in-service training; and (9) termination of provider agreement.

C. Impact of Adverse Survey Findings and Scope of Available Review

1. Use Of The Grid And SQC Standards

Penalties and remedial procedures are materially affected by the substantive rule under which a given deficiency is cited.⁴ Where a surveyor assigns a deficiency under 42 C.F.R. 483.13 (resident behavior and facility practices), §483.15 (quality of life) or §483.25 (quality of care) to box F, H, I, J, K or L⁵ of the Grid, the nursing facility is automatically classified as one that provides "substandard quality of care" (SQC). 42 C.F.R. 488.301. If a deficiency under a subpart of §483 other than the three listed above is cited, a facility is equally subject to penalties based on the scope and severity of its noncompliance, but the SQC designation is inapplicable. Whenever a facility is found by surveyors to render substandard quality care, the regulations mandate that notices of that designation be disseminated, *inter alia*, to all of the attending physicians of individuals admitted to the facility, and to state boards that license the facility's administrator. 42 C.F.R. 488.325(g), (h). SQC findings in three consecutive surveys subject a facility to immediate, mandatory termination from Medicare and/or Medicaid and denial of Medicare or Medicaid payment. 42 C.F.R. 488.414.

2. Loss Of Nurse-Aide Training Rights

As a condition of Medicare and Medicaid program participation, nursing homes are obligated by OBRA to ensure that all of their nurse-aides complete a nurse-aide training and competency evaluation program (NATCEP). 42 U.S.C. 1395i-3(b)(5), 1396r(f)(2). Nurse-aides, which comprise the majority of nursing

4. Under guidance published in the SOM, each regulation containing a condition of participation is subdivided into constituent elements referred to as "F Tags," each of which is assigned a number. After a survey is concluded, the survey agency issues a report in which each deficiency citation is identified by "F Tag" and scope and severity level assigned to that F Tag (i.e., category "A" through "L" on the Grid, JA 66).

5. For example, an "F" citation means that there is a failure to abide by an element of a condition of participation that is "widespread" and that has caused no actual harm, but has the potential to cause more than "minimal harm" but not "immediate jeopardy."

facility staff, may not be retained unless they are trained and certified within four months of employment. Facilities generally conduct their own NATCEPs under authority of 42 U.S.C. 1395i-3(f)(B), 1396r(f)(B). When a facility is "found" to provide SQC during a "standard survey," it is reflexively subjected to an "extended survey" and automatically barred from conducting nurse-aide training for a two-year period. 42 U.S.C. 1395i-3(g)(2)(B), and 1396r(g)(2)(B); 42 C.F.R. 483.151(b)(2); SOM §7210. Facilities "locked out" of conducting NATCEPs must procure training for all new employees from outside sources, if possible. If an alternative program is not locally available, and new staff cannot be trained and certified, the facility is subject to termination.

3. "Poor Performer" Status

Without the benefit of rulemaking, HCFA adopted the concept of a "poor performing" facility. SOM §7304.B. Any facility cited for a deficiency categorized as SQC in any two out of three surveys is labeled a "poor performer," and, as a result, automatically denied the opportunity to correct deficiencies by a "date certain" and thereby avoid the imposition of penalties. *Id.* By memorandum issued to State Agency Directors and HCFA Associate Regional Directors on September 22, 1998, HCFA unilaterally announced that in order "[t]o strengthen enforcement, the mandatory 'poor performing facility' criteria are being revised" and expanded to reach facilities cited for level "G" deficiencies "at the previous standard survey or any intervening survey." Through a second transmittal issued the same day, the Secretary urged States to treat all facilities within a nursing home chain as "poor performers" if another facility within the same chain — including one that is separately operated, licensed and incorporated, and located in a different geographic region — is found to be a poor performer. Because the Secretary did not mandate the uniform use of this approach, even under the SOM, application of this standard will necessarily vary from state to state. *Contrast* 42 U.S.C. 1396r(g), (h)(2)(B) and 1395i-3(g)(3)(D), (h)(2)(B).

4. Appeal And IDR Processes

Although it comprehensively amended the conditions of participation and enforcement rules, OBRA did not similarly amend

the provisions of the Act to address or limit administrative and judicial review. No new provisions were engrafted onto Title XIX. The language formerly codified in §1395ff(c), and recodified at §1395cc(h)(1) without substantive change by OBRA, states:

(h) Dissatisfaction with determination of Secretary; appeal by institutions or agencies; single notice and hearing. (1) Except as provided in paragraph (2), an institution or agency dissatisfied with a determination by the Secretary that is not a provider of services or with a determination described in subsection (b)(2) shall be entitled to a hearing thereon by the Secretary (after reasonable notice) to the same extent as is provided in section 205(b), and to judicial review of the Secretary's final decision after such hearing as is provided in section 405(g).

(2) An institution or agency is not entitled to separate notice and opportunity for a hearing under both section 1128 [42 U.S.C. §1320a-7] and this section with respect to a determination or determinations based on the same underlying facts and issues.

By regulation the Secretary independently has provided for administrative appeals before an ALJ from the imposition of certain of the sanctions delineated in 42 C.F.R. 488.406 in addition to terminations. 42 C.F.R. 431.151, 498.3(d). Unless a facility actually is subjected to one of the remedies listed in 42 C.F.R. 488.406 that the Secretary has categorized as a "determination subject to appeal," there is no right under the rules to an adjudicative hearing to contest the deficiency citation even if the citation also triggers a SQC or poor performer designation. 42 C.F.R. 431.151, 431.153(b), 498.3(d). No right to appeal exists from citations resulting in the installation of a State monitor. Where her rules permit an appeal, the Secretary has with minor exception⁶

6. The only exception applies to level of scope or severity findings that shift a violation from a lower to a higher "range" of civil monetary. 42 C.F.R. 431.153(b)(4). CMPs in the range of \$50 to \$3,000 per day may be imposed in the absence of "immediate jeopardy," while noncompliance that constitutes immediate jeopardy is subject to penalties ranging from \$3,050 to \$10,000 per day. 42 C.F.R. 488.408. A provider may challenge the level of the deficiency citation to the extent it impacts the permissible "range" of monetary penalties,

prohibited the provider from contesting the scope or severity of a deficiency and limited review to the question of whether the acts or omissions cited comprise a deficiency *vel non*. Additionally, where an appeal is permitted, the filing of an appeal generally does not stay the immediate imposition of a sanction. 42 C.F.R. 431.153(e)(2), (f)(1),(2).

Under 42 C.F.R. 488.331, the Secretary requires the State agency to "offer a facility an informal opportunity, at the facility's request, to dispute survey findings upon the facility's receipt of the official statement of deficiencies." This informal dispute resolution (IDR) process amounts to reconsideration by the same surveyors that levied the deficiency citation in the first place. IDR may be limited to a paper review, and "cannot delay the effective date of any enforcement action against the facility." 42 C.F.R. 488.331(b)(1), (2). Under rules found only in the SOM, HCFA has further prohibited facilities from contesting the surveyor's selection of remedies or the assignment of a given "scope" or "severity" level, even in the context of the IDR process. SOM §7212. There is no right to obtain review from an adverse disposition of an IDR request.

SUMMARY OF ARGUMENT

I.A. Although the Secretary relies heavily on *Heckler v. Ringer*, 466 U.S. 602 (1984), and *Thunder Basin Coal Co. v. Reich*, 510 U.S. 200 (1994), in contending that the lack of immediate judicial review of the Secretary's compliance with the APA or the Due Process Clause will be ameliorated by subsequent judicial review, administrative or judicial review is unavailable in most cases, even on a post-deprivation basis. Title XVIII directs the Secretary to provide appeals only when the State agency (or HCFA) has "terminated" or refused to renew a facility's Medicare certification or where a civil monetary penalty has been assessed. By regulation the Secretary has provided for administrative appeals from the actual imposition of certain of the seven other

under a narrow "clearly erroneous" standard of review. 42 C.F.R. 431.153(b)(4), (j), 498.3(d)(13). Accordingly, even in CMP cases, the scope and severity may not be challenged unless a facility is cited under level "D," "G" or "J" of the Grid, JA 66.

sanctions included within 42 C.F.R. 488.408. At the same time, the Secretary has refused to allow an adjudicative appeal from certain sanctions, such as orders appointing State monitors to oversee operations and otherwise severely limited providers' appeal rights.

In the vast majority of cases (over 96%), administrative appeal rights are rescinded before any adjudication can occur. "Regardless of which penalty is proposed," a facility independently is obligated to submit a plan to remediate the deficiencies cited by the surveyors regardless of whether it agrees or disagrees with the allegations and may be automatically terminated from the programs if it fails or refuses to do so. 42 C.F.R. 488.402(d)(1). If, however, the Plan of Correction is timely and adequate, the proposed "sanction" is withdrawn and the right to appeal from the underlying deficiency citation (and any other consequences that attach to it) that otherwise exists under the rules is "rescinded" in most instances. See *Country Club Center II v. HCFA*, DAB No. C-96-111 (Aug. 28, 1996), reprinted in (CCH) Medicare & Medicaid Guide ¶44,778. However, the adverse findings become a permanent part of the facility's record, and, depending on the scope and severity assigned, may prompt a designation that the facility provides substandard quality care or is a "poor performer" which sets another chain of adverse administrative actions into play.

Even where an adjudicative appeal is allowed, the Secretary has limited the issue and evidence that may be considered to whether a deficiency exists *vel non*, and has prohibited facilities from challenging the surveyor's scope or severity determinations or choice of a particular remedy. 42 C.F.R. 488.331(b). Consequently, the very issues that are at the core of respondent's complaint may not be considered in an administrative proceeding, and, except for an extremely narrow band of cases in which an individual provider actually has been fined or terminated, there is never any right to obtain subsequent judicial review under the Act itself. As a result, and "as a practical matter," the approach constructed by the Secretary affords the vast majority of facilities and individuals subject to the new system no "meaningful opportunity" for contesting the inherent limits in the process, or the legality of the Manual provisions and rules that drive the new

enforcement system. Accordingly, this case is controlled not by *Ringer*, but by *Bowen v. Michigan Academy of Family Physicians*, 476 U.S. 667 (1986) (*Michigan Academy*).

I.B. The Secretary's position is all the more indefensible because it would foreclose most providers from obtaining judicial review of substantial constitutional claims. It is no small irony for the Secretary to insist that eventual judicial review will satisfy Due Process requirements where one of respondent's most fundamental concerns is that the Secretary's enforcement and review system inherently denies facilities (and their administrators) Due Process because it is calculated to preclude even post-deprivation review. Unappealable deficiency citations that result in an SQC designation simultaneously trigger the mandatory dissemination of damaging public notices that the facility provides substandard quality services. These notices go to the treating physicians who often refer their patients to the facility, among others, and seriously damage morale and the reputation of the home within its community. These harms are exacerbated by the Secretary's recent launch of an Internet web site in which this information is posted for review by two hundred million Americans.

Although the level and timing of penalties to which a facility may be subject are based on the facility's past performance, facilities are not only denied the right to a contemporaneous appeal for most citations, but the Secretary has further prohibited them from contesting deficiencies cited during earlier surveys even when they later serve to transform the facility into a "repeat offender" and aggravate sanctions. Until weeks ago, the Secretary had also denied appeal rights from deficiency citations that automatically prompt the revocation of a facility's right to conduct training and competency programs for their nurse-aides — the procurement of which is a mandatory condition of Medicaid and Medicare participation — for two years. This is akin to withdrawing a license, and the economic and practical problems caused by such lock-outs has now essentially been conceded by the Secretary, 64 Fed. Reg. 39934, 39935 (July 23, 1999). Such deprivations may not be inflicted without affording a facility Due Process of law. *Paul v. Davis*, 424 U.S. 693, 700 (1976); *Board of Regents v. Roth*, 408 U.S. 564, 573 (1972).

The only protection afforded against erroneous deprivations in these instances is a highly informal dispute resolution process before the same state survey agency that imposed the deficiency, which may be limited to a paper review and includes no right to make a record or to examine witnesses. Even in this context the Secretary has prohibited the consideration of the scope or severity of the alleged violation or the choice of penalty. Particularly given the absence of any subsequent right to obtain judicial review, *Zimmerman v. Burch*, 494 U.S. 113 (1990), respondent has made out more than a colorable claim that this approach does not afford Due Process.

II. This Court's analysis must "begin with the strong presumption that Congress intends judicial review of administrative action" which can be overcome only by "clear and convincing evidence" to the contrary. *Michigan Academy*, 476 U.S. at 670. *Accord McNary v. Haitian Refugee Ctr., Inc.*, 498 U.S. 479, (1991) (*McNary*). For several reasons, the Secretary cannot sustain this burden.

A. The provisions on which the Secretary would rest the preclusion of judicial review under §1331 were incorporated from Title II of the Act under a pre-OBRA provision of Title XVIII that pertains only to review of terminations of individual facilities from the Medicare program or refusals to renew Medicare certifications. No comparable review-limiting provisions exist under Title XIX, and the rules and guidelines challenged by respondent overwhelmingly impact Medicaid (not Medicare) program participation. In direct contrast with Medicaid, which (at 71.9% of all resident days) is the single largest payer, Medicare coverage of long term care is extremely narrow.

The limited incorporated bar on the exercise of federal jurisdiction under 42 U.S.C. 1395ii for facilities that seek prematurely to challenge a proposed Medicare termination in district court is a scant basis to conclude that Congress clearly intended to bar all manner of systemic challenges under the APA and the Due Process Clause to rules that principally impact Medicaid program participation. See *Woodstock/Kenosha Health Ctr. v. Secretary of HHS*, 713 F.2d 285 (7th Cir. 1983). The Secretary's position also is refuted by the legislative history.

Although the Secretary would ignore this fact, the Act was amended to impose specific duties and rulemaking requirements upon the Secretary in "direct[] response to the district court's opinion in [the *Smith*] case." *Estate of Smith v. Heckler*, 747 F.2d at 590 n.3. Congress had every opportunity to limit or preclude judicial review when it comprehensively amended the Act in 1987 (and in many years since). Instead, in enacting the OBRA reforms Congress took direct cognizance of the "Court order" in *Smith* compelling HCFA to "revis[e] the current survey process." H.R. Rep. No. 100-391(I), 100th Cong. 1st Sess. at 452, reprinted in 1987 U.S.C.C.A.N. 2313-1 at 2313-272. This recognition, coupled with the omission of any review-limiting provisions pertaining to the new intermediate sanction rules, is tantamount to a congressional endorsement of jurisdiction.

B. As the lower court recognized, the Medicare provisions on which the Secretary would rely to preclude any systemic judicial review of the survey and enforcement system are designed only to prevent premature judicial review of fact-specific penalty determinations by facilities for which the Act provides an on-record post-deprivation hearing before an ALJ. This case is a generalized systemic challenge to the rules that establish the overall processes for enforcement and review and the claims held reviewable below "arise under" the APA and the Due Process clause, not the SSA. Rather than *Ringer* or *Thunder Basin Coal Co.*, this case is accordingly governed by *Michigan Academy* and *McNary*, which underscore "the critical difference" between a collateral challenge to the rules and processes by which decisions are made, and a challenge to a sanction imposed or payment due in "an individual [case]." 498 U.S. at 497.

ARGUMENT

I. THE APPEALS SYSTEM ADOPTED BY THE SECRETARY PROVIDES NO AVENUE FOR JUDICIAL REVIEW AND TOTALLY FORECLOSES REVIEW OF CONSTITUTIONAL ISSUES IN THE VAST MAJORITY OF CASES

A. The Secretary's Argument That The Instant Claims Must Be Channeled Through The Administrative Process Intentionally Ignores The Substantial Lack Of Administrative Appeal Rights

Relying heavily on *Heckler v. Ringer*, 466 U.S. 602 (1984), and *Thunder Basin Coal Co. v. Reich*, 510 U.S. 200 (1994), the Secretary contends that 42 U.S.C. 405(h), as incorporated into Title XVIII (Medicare) by 42 U.S.C. 1395ii and 1320a-7, precludes respondent from invoking federal question jurisdiction to challenge the Secretary's regulatory scheme under the APA or the Constitution without first exhausting administrative remedies. This argument is inextricably linked to the Secretary's insistence that these claims ultimately will be preserved for judicial review under 42 U.S.C. 1395ii and 405(g) once the administrative appeal process has been exhausted. That premise, however, is simply false: in most cases and for most of the issues raised below, there are no administrative (let alone judicial) remedies available to facilities. Consequently, the real issue presented is not whether *eventual* judicial review is meaningful or adequate as the Secretary asserts (*see* Pet. Br. at 49-50), but whether the Secretary may lawfully deprive nursing homes of *any* mechanism to obtain judicial review.

This litigation is a systemic challenge to shortcomings in the enforcement and review scheme that extend far beyond termination cases and are largely beyond the compass of §1395c(h). Section 1395cc(h) provides for an adjudicative proceeding only in the limited instances where a provider has been terminated or excluded from the Medicare program, or assessed a CMP. By regulation, the Secretary has provided for post-deprivation adjudicative proceedings for certain other penalties included in

§488.406. However, the right to an adjudicative appeal is limited to situations where a provider actually has been subjected to those sanctions. 42 C.F.R. 498.3(b)(12) (Medicare), 431.151(a), incorporated by 42 C.F.R. 488.330(e)(4) (Medicaid). *See, e.g., Arcadia Acres, Inc. v. HCFA*, DAB-AD-1607 (Jan. 22, 1997), reprinted in (CCH) Medicare & Medicaid Guide ¶45,140; *Rafeal Convalescent Hosp. v. HCFA*, DAB-CR-444 (Nov. 19, 1996), reprinted in (CCH) Medicare & Medicaid Guide ¶45,241; *Waterman Convalescent Hosp. v. HCFA*, DAB-AB-1548 Docket No. A-96-22 (Nov. 13, 1995).

In no case will an appeal lie from "the imposition of State monitoring, the loss of the approval for a nurse-aide training program," or a deficiency finding by a surveyor requiring the submission of a plan of correction (POC). 42 C.F.R. 431.153(b). In other cases the right to appeal is more apparent than real. Any provider found not in "substantial compliance" with substantive program conditions (i.e., is cited for any deficiency under Part 483 that places in Grid boxes "D" through "L," JA 66) is legally obligated to submit a POC for approval by HCFA or the State survey agency "regardless of which remedy" has been proposed, and terminated from the programs if it fails or refuses to do so. 42 C.F.R. 488.402(d)(1). If, however, the POC is found acceptable because the provider has corrected the alleged deficiencies (even though it simultaneously contests the citation), the proposed sanction is not imposed (unless the facility has already been branded a "poor performer" as a result of prior surveys). At that point, the right to appeal is "rescinded" under the regulations. *See Country Club Center II v. HCFA*, DAB No. C-96-111 (Aug. 28, 1996), reprinted in (CCH) Medicare and Medicaid Guide ¶45,240; *University Towers Medical Pavilion v. HCFA*, DAB-CR-436 (Sept. 12, 1996), reprinted in (CCH) Medicare & Medicaid Guide ¶44,778.

Stated otherwise, the Secretary has created a "Catch 22." Facilities are obligated to undertake prompt corrective action notwithstanding the pendency of an appeal from a deficiency citation, and regardless of whether they dispute the underlying deficiency citation. As a practical matter, a facility cannot meaningfully preserve its appeal rights by declining to submit a POC (as the Sixth Circuit appeared to conclude in *MAHSA*), since it is

independently subject to termination for failing to submit a POC. A facility that takes steps "required" by regulation and timely corrects the alleged deficiencies loses the right to challenge the underlying citation, which is permanently etched into its record. As a result, it is saddled with the permanent deficiency citations, the loss of nurse-aide training rights, and the issuance of damaging notices to licensing boards and to treating and referring physicians.

A facility thus deprived of the right to challenge the deficiency citation also remains subject to enhanced and accelerated sanctions in future surveys under the poor performer rule adopted informally through the SOM, or the repeat offender standards the Secretary has adopted for SQC facilities. Under a complementary rule adopted solely through the SOM, the Secretary has further decreed that providers that become subject to enhanced or accelerated penalties as a result of (nonappealable) deficiency citations in prior survey cycles may *not later challenge* the earlier citations, even when they serve to compound a sanction under the repeat offender standards. SOM §§7303, 7304(A), 7320. This would be analogous to subjecting a person to a higher minimum penalty or longer prison term under federal sentencing guidelines based on recidivism in the absence of any right to contest the prior offenses. Even the agency's Departmental Appeal Board has described this limitation as constitutionally suspect. *Fort Tryon Nursing Home v. HCFA*, DAB CR-425 (July 3, 1996), reprinted in (CCH) Medicare and Medicaid Guide ¶44, 514.

While the Secretary's review of the regulatory scheme essentially ignores all cases for which no administrative appeal (let alone judicial review) actually is available, these represent the *vast majority* of cases. Governmental statistics illustrate that 21,351 nursing home surveys occurred from July 1, 1995 through January 1, 1996 (8711 "standard surveys" plus 12,640 "complaint surveys"). JA 77. Penalties ranging from State monitoring to termination were proposed in 14,386 cases. JA 78. These culminated in the actual imposition of a sanction that would enable the facility to pursue an administrative appeal in 523 instances (629 remedies imposed, including 106 cases resulting in "State monitoring" for which no appeal is permitted under 42 C.F.R. 498.3(d)(10)(iii)). Accordingly, the right to challenge the survey-

ors' findings before an administrative law judge, along with any eventual right to judicial review following the "exhaustion" of administration remedies under Title XVIII, was actually extended in only 3.6% of the nationwide surveys in which deficiencies were cited (523/14,386). Conversely, there was *no right* to an adjudicative appeal in over 96% of such cases.

The Secretary acknowledges that the legality or constitutionality of her rules may not be considered by an ALJ or on appeal to the DAB, but suggests that the eventual right to obtain review in federal court under the SSA will cure this problem. For example, the Secretary states that the imposition of a CMP gives rise to direct appellate review under §1395cc(h)(2), and, on the putative basis of §1395cc(h)(1), that "[i]n all other cases, 'judicial review of the Secretary's final decision' is available in district court as provided in 42 U.S.C. 405(g)." Pet. Br. at 11 (emphasis added). That representation is misleading.

Section 1395cc(h)(1) makes judicial review available "to the same extent as provided in section 405(b) of this title" for "a determination described in subsection (b) of this section." Since subsection (b)(2) relevantly pertains only to a determination of the Secretary to "terminate" a provider agreement, the logical import of the Secretary's argument is that *no review is available in district court* following an administrative hearing that does not result in a "termination." Unreviewable cases include those, *inter alia*, where payments have been denied for Medicare recipients. Out of the 523 instances in which an administrative appeal actually was available, only twenty-one (21) involved terminations. JA 78. Accordingly, if we understand the Secretary's position, only .14% of cases involving deficiency citations leading to proposed sanction (21/14,386) would ever qualify for review in which challenges to the legality and constitutionality of the rules and Manuals might be advanced in district court.⁷

7. 42 U.S.C. 1395i-3(h)(2)(B)(ii), read in conjunction with §1320a-7a(e), separately provides for direct review in the United States Court of Appeals for cases in which a civil monetary penalty has been imposed upon a facility after a hearing. If direct appeals to the U.S. Courts of Appeals were added to terminations, a total of 0.7% of the cases in which deficiencies were cited (115/14,386) eventually became eligible for judicial review.

The fact that a small percentage of facilities ultimately might be entitled to contest a remedy that has been applied to them, and that an even smaller number might be entitled to subsequent judicial review in which the legality of the underlying rules might be challenged does nothing to protect or preserve the rights of the vast majority of providers afforded no viable avenue for seeking relief against the flaws in the system. This includes facilities that are branded as substandard, deprived of the ability to conduct nurse-aide training and certification, or mandatorily subjected to increased penalties as recidivists due to deficiency citations which they may never challenge on their behalves. Indeed, it is doubtful that a facility that obtains the right to review under 42 U.S.C. 1395cc(h) and §405 of the SSA because it actually has been terminated (or subjected to CMPs) following an administrative determination would even possess standing (let alone the incentive) to challenge the system's denial of hearing rights to other parties or its impact on other providers that have gone before it. See *Singleton v. Wulff*, 428 U.S. 106, 113 (1976); *Barrows v. Jackson*, 346 U.S. 249, 255 (1953).

In the limited instances where an administrative appeal right exists, severe limitations on the scope of review undermine its meaningfulness. Although a provider actually subjected to a sanction is afforded granted the right to a post-deprivation administrative hearing, the Secretary has by regulation which binds the ALJ and DAB members *limited* the issues and the evidence that may be considered to whether or not an alleged act or omission constitutes a deficiency (i.e., non-compliance with a substantive standard) *prohibited* providers from contesting the "scope or severity" the surveyors attach to a violation based on the unexplained standards embodied in 42 C.F.R. 488.404 and the Grid. 42 C.F.R. 431.151(b), (c), (e); 498.3(d)(12).⁸ Even in the highly informal context of IDR, the Secretary prohibits consideration of

8. A lone partial exception to the Secretary's ban on challenging the scope and severity assigned to a violation under the Grid applies to CMP cases. See *supra* at 10 n. 6. Even then, the Secretary has systematically discouraged appeals by offering a 35% "discount" of CMPs for facilities that agree to waive their rights to a hearing within 60 days of their receipt of notice of the penalty. 42 C.F.R. 488.436.

the scope and severity assessment or choice of penalty imposed by HCFA or the State agency. 42 C.F.R. 488.331(b); SOM §7212(c)(2).

Accordingly, neither the legality of the very standards that lie at the heart of the complaint in this case (and in *MAHSA v. Shalala*) nor the facts that go to the level of a deficiency citation or choice of penalty may be considered when cases proceed to an administrative appeal. See e.g., *Beverly Health & Rehabilitation - Springhill v. HCFA*, DAB-CR-553 (Oct. 27, 1998), reprinted in (CCH) Medicare & Medicaid Guide ¶120,033; *Brighton Pavilion v. HCFA*, DAB-CR-510 (Dec. 10, 1997). This additionally prevents facilities as a "practical matter" from obtaining "meaning judicial review" of "the types of claims raised in this litigation." *McNary*, 498 U.S. 476 at 496-97 (1991). *Contrast Thunder Basin Coal Co.*, 510 U.S. at 781-82 (meaningful post-deprivation hearing eventually is available to address the same claims over which plaintiff sought to obtain immediate review); *Reno v. Catholic Soc. Servs.*, 509 U.S. 43, 60, 62 (1993) (meaningful judicial review includes "the opportunity to build an administrative record on which judicial review might be based").⁹

B. The Secretary's Appeal Rules Preclude Judicial Review of Colorable Constitutional Claims

The Secretary's approach is all the more invidious because it absolutely prevents providers from advancing substantial constitutional claims. As this Court has instructed:

When constitutional questions are in issue, the availability of judicial review is presumed, and we will not read a statutory scheme to take the "extraordinary" step of foreclosing jurisdiction unless Congress' intent

9. In *Catholic Soc. Servs.*, the Court held that *McNary* supported the exercise of federal question jurisdiction over challenges to the "front-desk" treatment of an application under the IRA that would preempt subsequent review, and remanded the matter for consideration of whether this approach had been applied to class members. As noted in Justice O'Connor's concurring opinion, ripeness is far more of an issue where a party seeks to challenge the application of a benefit-granting rule that has not yet been applied to him, then it is in a suit challenging a duty-creating rule (such as the present case). 509 U.S. at 68.

to do so is manifested by "clear and convincing" evidence. [Weinberger v. Salfi], 422 U.S. [749] at 762; *Johnson v. Robison*, 415 U.S. 361, 366-6 (1974).

Califano v. Sanders, 430 U.S. 99, 109 (1977). Accord *Bartlett v. Bowen*, 816 F.2d 695, 699 (D.C. Cir. 1987). *Parker v. Califano*, 644 F.2d 1199, 1201 (6th Cir. 1981) (reversing denial of jurisdiction under §405 of Due Process challenge to adequacy of "notice and opportunity to be heard"). The right to immediate judicial review is particularly worthy of protection where it includes a Due Process based challenge to the adequacy of the very notice and hearing procedures the Secretary has promulgated. See *Himmeler v. Califano*, 611 F.2d 137, 148 (6th Cir. 1979).

It is no small irony for the Secretary to insist that eventual judicial review will cure any Due Process concerns where one of respondent's central complaints is that the Secretary has totally foreclosed the right to any review in most instances and for most facilities impacted by the enforcement scheme. Findings that serve to compound, heighten and accelerate the imposition of present and future sanctions are unappealable as are most determinations of the scope or severity of the violation, despite the ratcheting effect they have on present and future sanctions. With the limited exception of a highly informal IDR conducted by the surveyors, the system includes no right to contest deficiency findings that mandate the conclusion that a facility provides substandard care. This finding, in turn, irreversibly triggers the issuance of notices to, *inter alia*, the physicians who treat and refer nursing home residents, and must certify individuals for admission to a skilled nursing facility under the Secretary's rules. See 42 C.F.R. 488.325(g), (h). Moreover, in *MAHSA v. Shalala*, the Secretary candidly admitted for the record that the severe restrictions placed on provider appeal rights were motivated by administrative convenience and cost considerations. See *Vlandis v. Kline*, 412 U.S. 441, 450 (1973); *Stanley v. Illinois*, 405 U.S. 645, 656 (1972) ("the Constitution recognizes higher values than speed and efficiency").¹⁰

10. On March 18, 1999, the Secretary issued a final rule with comment period which narrows the category of cases in which the imposition of a civil monetary penalty may be deferred pending corrective action that might serve to

Respondent here and plaintiffs in *MAHSA* alleged and demonstrated that branding a facility as substandard, combined with targeted dissemination of that information by a government agency, damages its reputation in the community¹¹ and carries tangible financial consequences and other burdens in the form of curtailed admissions, collateral review by state agencies that license nursing home administrators, added training costs, and barriers to hiring staff. Government may not prompt such deprivations without satisfying Due Process requirements. See *Paul v. Davis*, 424 U.S. 693, 700 (1976); *Board of Curators v. Horowitz*, 435 U.S. 78 (1978); *Board of Regents v. Roth*, 408 U.S. 564, 573 (1972) (due process requires opportunity to refute public dissemination of contested information that stigmatizes or impinges on reputation or which may foreclose other business or employment opportunities). Provisions of the Act must be construed, if reasonably possible, in a manner that avoids Constitutional infringements, see *DeBartolo Corp. v. Florida Coast Bldg. and Constr. Trades Council*, 485 U.S. 568, 574 (1988); *Gomez v. United States*, 490 U.S. 858, 864 (1989), which further mitigates against the Secretary's expansive reading of §1395ii.

The reputational plus financial injury — from which the Secretary provides no meaningful way to obtain review in most cases — is compounded by the fact that the Secretary has not only required the public posting and distribution of deficiency reports, 42 C.F.R. 488.325, but has by recent administrative decree created an Internet website entitled "Nursing Home Compare" (<http://www.medicare.gov/nursing/home.asp>), through which the unappealable deficiency citations and substandard care designations are disseminated to millions of consumers and professional peers of facility administrators. Widespread dissemination of a potentially inaccurate characterization about the quality of care a

abate the penalty, and authorizes the immediate imposition of a CMP based on a set of criteria that include the "facility's history of prior offenses." 64 Fed. Reg. 13354, 13357 (Mar. 18, 1999). This further compounds the impact of the regulatory limitations the Secretary has placed on provider appeals.

11. As Michigan's State survey chief attested in *MAHSA v. Shalala*, "when a facility is designated" a poor performer, "morale is just devastated and key people are disenchanted because . . . it certainly portrays the facility in a less than flattering manner in the community."

nursing facility renders can be particularly devastating when the facility is a non-profit entity operated by a religious order or fraternal organization.

In addition to triggering repeat offender status and the widespread dissemination of damaging information without the benefit of a prior or subsequent adjudicative process, the surveyors' assignment of a given scope and severity level to an alleged deficiency can cause a two-year revocation of a facility's federal authorization to conduct NATCEP programs for their unlicensed staff. Training and certification is a mandatory condition of Medicaid and Medicare program participation. Revocation of the right to provide such training is analogous to the revocation of a license and thereby additionally warrants Due Process protection. See generally *Barry v. Barchi*, 443 U.S. 55 (1979) (state's suspension of a horse trainer's license implicates deprivation of a property interest protected by the Due Process Clause and requires a post-suspension hearing); *Bell v. Burson*, 402 U.S. 513, 539 (1971) (whether the entitlement to a driver's license is a right or a privilege, the State's termination of a license whose "continued possession may become essential in the pursuit of a livelihood" is subject to due process protection). Adequate protection against errors and the injuries is not afforded by the IDR process, particularly given the absence of any right to a name-clearing adjudication or subsequent judicial review in which the effects of the SQC citation might be reversed even after the information has been disseminated. See *Roth*, 408 U.S. at 573. To say the least, respondent has raised a colorable Due Process claim, especially given the absence of any subsequent right to judicial review to protect against erroneous deprivations flowing from the lack of an administrative adjudication. See *Zimmerman v. Burch*, 494 U.S. 113 (1990).

After filing her brief on the merits, the Secretary published an "interim final rule" that will in the future enable providers to separately appeal from SQC determinations that cause a facility to lose the approval of its nurse-aide training and evaluation program. 64 Fed. Reg. 39934 (July 23, 1999). In liberalizing the appeal procedures, the Secretary observed:

Facilities have had the ability to challenge the loss of their nurse aide training program only if they were

challenging the imposition of a remedy that was appealable.... We believe, however, that we should acknowledge the arguments that have been advanced by individual facilities as to the magnitude of the loss to them when they are unable to train nurse aides themselves. Facilities have alerted us to the difficulty they sometimes have in finding qualified nurse aides once they are unable to train their own.... Turnover in these positions is high, thereby placing increased pressures on facilities to maintain staff they need to furnish essential services to faculty residents. Thus, the loss of an ability to train nurse aides can have significant consequences for a facility. (*Id.* at 39935; emphasis added.)

This belated partial repair of the problem strongly reinforces respondent's arguments that the historic refusal to provide an appeal from citations prompting this remedy offends due process. Unfortunately, this rule is too little and too late for those providers subjected to a NATCEP lock-out prior to its effective date, and it offers no relief to any provider subject to enhanced penalties for deficiency citations that do not also trigger a lock-out.

II. THE SECRETARY CANNOT SATISFY HER BURDEN OF DEMONSTRATING THAT CONGRESS INTENDED TO PRECLUDE JUDICIAL REVIEW OF THE MATTERS RAISED IN RESPONDENT'S COMPLAINT

This Court's analysis must "begin with the strong presumption that Congress intends judicial review of administrative action," *Michigan Academy*, 476 U.S. at 670. Accord *McNary*, 498 U.S. at 496, 498. See also *Colorado River Water Conservation District v. United States*, 424 U.S. 800, 817 (1976) (there is a "virtually unflagging obligation of federal courts to exercise the jurisdiction given them"); *Wilcox v. Consolidated Gas Co.*, 212 U.S. 19, 40 (1908). That presumption may be overcome only by "clear and convincing evidence" that Congress intended to preclude jurisdiction. *Michigan Academy* at 670, 680, citing *Abbott Labs. v. Gardner*, 387 U.S. 136, 141 (1967); *McNary*, *supra*. The secretary cannot sustain that burden here.

A. The Narrow Review-Limiting Provisions Incorporated Under Title XVIII Of The Act Do Not Evinced A Clear and Convincing Intent To Abrogate Systemic Review of Rules Principally Applied Under Title XIX

The Secretary treats this case as though it exclusively involves the Medicare program. This is not surprising given the Secretary's reliance on review-limiting provisions of the Act — including 42 U.S.C. 1395cc(h) and 1395ii, which in turn incorporate 42 U.S.C. 405(g), (h) from Title II — that apply exclusively to Medicare, and the fact that Title XIX, 42 U.S.C. 1396 *et seq.*, "lacks any comparable restriction." *Illinois Council*, 143 F.3d at 1047. Consequently, the Secretary is reduced to arguing that the incorporation by reference of narrow jurisdiction-limiting provisions in the Medicare Act is "clear and convincing" proof that Congress intended to preclude systemic legal challenges to program rules whose principal impact is under Medicaid, where no provision of law limits or precludes review. That proposition is even more of a stretch in view of the fact that Medicare coverage extends to only a small fraction of nursing home residents (8%) as compared with Medicaid (72%) (see page 5, *supra*), and it turns the presumption in favor of jurisdiction on its head. See *Woodstock Kenosha Health Ctr. v. Secretary of HHS*, 802 F.2d 870 (7th Cir. 1983). It is also contrary to the legislative history.

In enacting OBRA, Congress took direct cognizance of the "Court Order" in *Smith* that had compelled HCFA to "revis[e] the current survey process." H.R. Rep. No. 100-391(I), 100th Cong. 1st Sess. at 452, reprinted in 1987 U.S.C.C.A.N. 2313-1 at 2313-272. Congress had every opportunity to amend Title XIX to mandate the exhaustion of administrative remedies or preclude the exercise of general federal question jurisdiction to challenge the newly adopted standards in radically revising the survey and enforcement scheme, but did not do so.¹² Instead, in comprehensively amending the Act to provide for new and expanded sanctions, Congress required the Secretary to utilize regulations and

12. These provisions were again amended in 1992, 1996 and 1997 by the Older Americans Act of 1992, Pub. L. No. 102-375, 106 Stat. 1195; the Nursing Home Facility Resident Reform Act, Pub. L. No. 104-315, 110 Stat. 3824; and the Balanced Budget Act of 1997, Pub. L. No. 105-33, 111 Stat. 251, respectively.

pursue national consistency in administration of the survey and enforcement scheme consistent with the judicial relief ordered in *Smith*. If anything, this recognition, coupled with the omission of any bar on the exercise of federal question jurisdiction in OBRA, is tantamount to a congressional ratification of juridical oversight. See generally *Davis v. Michigan Dept. of Treas.*, 489 U.S. 803, 811 (1989) (codification of a judicial determination as endorsement); *Lorillard v. Pons*, 434 U.S. 575, 580-81 (1978) (reenactment of law with awareness of judicial determination as ratification of the same); *Wilder v. Virginia Hosp. Ass'n*, 496 U.S. 498, 517 (1990). The Secretary's contrary approach would only further the very mischief Congress sought to address in enacting OBRA.

B. Respondent's Claims Do Not "Arise Under" The Medicare Act

Finally, as the Seventh Circuit recognized, the provisions on which the Secretary would rely to preclude systemic judicial review of the rules and guidelines under both programs were not intended to preclude the claims being advanced by the respondent even as they pertain exclusively to Medicare participation.

The Secretary contends that the claims at bar "arise under" the Medicare Act, and, based upon *Heckler v. Ringer*, asserts that §405(h) accordingly bars judicial review except to the extent it is specifically authorized by 42 U.S.C. 1395cc(h) and 405(g). *Ringer*, however, involved individual providers' efforts to obtain judicial review concerning claims-specific payments under Medicare. This Court observed that the result sought by plaintiffs in the form of a suit for declaratory relief was "inextricably intertwined" with a claim for benefits and, "at bottom" and "in substance," a judicial determination of a coverage issue that would be controlling of individual claims for payment of Medicare benefits. 466 U.S. at 614, 622, 624. See also *McNary*, 498 U.S. at 490, 494-95 (preclusion of jurisdiction attaches to cases involving "individual [claims] determinations" or which at their essence involve a "claim of entitlement to payment").

Accordingly, *Ringer* was limited to interdicting immediate judicial challenges to the amount being paid to providers for specific services in derogation of 42 U.S.C. 1395cc and 405(h). To the extent the phrase "arising under" the Act in § 405(h) is deemed synonymous with a claim that is not cognizable under

federal question jurisdiction, only individualized claims for relief are properly characterized as "arising under" Title XVIII under *Ringer* and in *Michigan Academy*.

Under 42 U.S.C. 1395cc(h)(1), the Medicare Act relevantly bars direct access to federal district court only to a facility challenging a determination that "it is no longer a provider." Section 1395cc(h) is the only provision that limits judicial review of matters relating to the OBRA survey and enforcement scheme. Originally codified at 42 U.S.C. 1395ff, §1395ii(h)(1) predates the adoption of "intermediate" sanctions and is a vestige from the pre-OBRA remedial scheme. By its plain terms, §1395cc(h) creates an entitlement to an on-record adjudicative hearing and subsequent judicial review for a facility that seeks review from a "final decision after [a] . . . hearing . . . provided [for] in section 405(g) of [Title 42]." As incorporated *mutatis mutandis* by §1395ii, §405(h) provides that "findings and decisions" concerning "individuals who were parties . . . [to] hearings" authorized by §405(b)(2) "shall be binding on all individuals who were parties to such hearings," and concomitantly prohibits the direct exercise of jurisdiction, under 28 U.S.C. 1331 or 1346 to "recover on any claim arising under" the Act. Unless the last sentence of §405(h) is read as if it is unconnected to the first two sentences of §405(h), the preclusion of §1331 review is inextricably interrelated to the types of matters and determinations to which §405(g) and §1395cc(h) apply. Certainly, that construction is heavily favored by the settled interpretive principle that establishes a presumption in *favor* of judicial review.

Unlike *Ringer*, this case does not involve an entity seeking to leap-frog over an ALJ or DAB hearing. Respondent does not challenge the adequacy of payment for particular services, or, for that matter, the imposition of a given sanction or penalty to any particular provider. Nor would a judgment predetermine the outcome of a specific result in any particular case. Rather, this is a collateral systemic challenge to the Secretary's use of Manuals to fashion important substantive standards, and to the severe restrictions the rules impose on providers' efforts to secure judicial review of adverse actions and determinations that for the most part do not involve "terminations" and which are not inextricably intertwined with an individualized claim for relief.

Respondent's position finds strong support in *McNary*. In *McNary* the Court examined a provision of the Immigration Reform and Control Act (IRA) that expressly authorized administrative review but foreclosed judicial review of certain adjudicative determinations by the Attorney General that might result in deportations. Plaintiffs sought to challenge the regulatory scheme the INS had adopted for processing deportation decisions on a systemic basis under the Act and the Due Process Clause. Relying heavily on this Court's analysis of §405 of the SSA in its "unanimous holding" in *Michigan Academy*, the Court found it "most unlikely" that the IRA's flat bars to administrative and judicial review in individual cases, 8 U.S.C. 1160(e), were intended to preclude a systemic challenge to aspects of the regulatory scheme on statutory or constitutional grounds. 498 U.S. at 496-98. Stressing that Congress abhors situations where there is "no review at all of substantial statutory and constitutional challenges to the Secretary's administration of . . . the Medicare program," the Court concluded that the review-limiting provisions of the IRA were aimed at individualized deportation determinations, not at the manner in which all claims are processed under the "newly . . . prescribed [regulatory] procedure" *Id.* at 495, 498. As *McNary* observed in looking to the analogous provisions of the Medicare Act, there is a "critical difference between an individual amount determination" and a challenge to the procedures for making such determinations." *Id.* at 498. As in *McNary*, respondent herein does "not seek a substantive declaration" about the merits of any particular penalty being applied to any particular facility.¹³

The Secretary expends much effort arguing that not all relevant provisions of the Medicare Act on which she relies pertain to determinations of "amounts," and asserting on that basis that the court below construed *Ringer* too narrowly and misapplied

13. *McNary* also emphasized that jurisdiction over collateral challenges to the hearing system itself was presumed even though individual relief might flow *indirectly* from such review: "Unlike the situation in *Heckler*, individual respondents in this action do not seek a substantive decision that they are entitled to SAW status. . . . Rather if . . . [they] prevail in this action, respondents would only be entitled to have their case files reopened and their applications reconsidered in light of the newly prescribed INS procedures." *Id.* at 495.

Michigan Academy to this case. As *McNary* recognized in analogizing to *Michigan Academy*, however, the issue is not whether payment of an "amount" of money is at stake, but whether the provisions that limit review involve the resolution of individualized claims for relief. Similarly, in revalidating the decision in *McNary*, the Court explained in *Reno v. Catholic Soc. Servs., Inc.*, that the statutory limitations imposed on judicial review under the statute at issue in *McNary* "describes the denial of an individual application [for relief] . . . and thus' applies only to review of denials of individual applications." 509 U.S. at 55, quoting *McNary*, 498 U.S. at 498, 494. Accord *Thunder Basin Coal Co.*, 510 U.S. at 771 ("petitioner's claims are "pre-enforcement" only because the company sued before a citation was issued").

CONCLUSION

The judgment of the Court of Appeals should be affirmed.

Respectfully submitted,

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Supreme Court of the United States CLERK

DONNA E. SHALALA, SECRETARY OF HEALTH AND HUMAN
SERVICES, ET AL., PETITIONERS

v.

ILLINOIS COUNCIL ON LONG TERM CARE, INC., RESPONDENT

ON WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE SEVENTH CIRCUIT

BRIEF FOR THE AMERICAN MEDICAL ASSOCIATION,
AMERICAN ACADEMY OF DERMATOLOGY, AMERICAN
ACADEMY OF FAMILY PHYSICIANS, AMERICAN ACADEMY
OF ORTHOPAEDIC SURGEONS, AMERICAN ASSOCIATION
OF MEDICAL COLLEGES, AMERICAN ASSOCIATION OF
NEUROLOGICAL SURGEONS-CONGRESS OF
NEUROLOGICAL SURGEONS, AMERICAN COLLEGE OF
OBSTETRICIANS AND GYNECOLOGISTS,
AMERICAN COLLEGE OF PHYSICIANS-AMERICAN SOCIETY
OF INTERNAL MEDICINE, AMERICAN SOCIETY OF
CATARACT AND REFRACTIVE SURGERY, AND ILLINOIS
STATE MEDICAL SOCIETY
AS AMICI CURIAE IN SUPPORT OF RESPONDENT

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INTEREST OF AMICI CURIAE¹

The American Medical Association ("AMA"), a private, voluntary, nonprofit organization, is the largest association of physicians in the United States. The AMA was founded in 1847 to promote the science and art of medicine and the improvement of the public health. Its nearly 300,000 members practice in all fields of medicine.

The American Academy of Dermatology ("AAD"), a nonprofit organization representing 12,000 physicians specializing in the practice of dermatology, is the largest organization of dermatologists in the world. Founded in 1938, AAD is dedicated to maintaining the highest standards of clinical practice, education, and medical research pertaining to dermatology.

The American Academy of Family Physicians is a national medical specialty society representing over 88,000 family physicians, family practice residents and medical students. Its members provide comprehensive, coordinated and continuing care to all members of the family and serve as the patient's advocate in the changing health care system.

The American Academy of Orthopaedic Surgeons ("AAOS") is a nonprofit organization representing 18,000 board-certified orthopaedic surgeons. Founded in 1933, the AAOS provides continuing medical education for its members and allied health professionals to help maintain a high level of skill and competence in the practice of orthopaedic surgery.

¹The parties have consented to the submission of this brief. Their letters of consent have been filed with the Clerk of this Court. None of the parties authored this brief in whole or in part and no one other than *amici*, their members, or counsel contributed money or services to the preparation or submission of this brief. See Sup. Ct. R. 37.6.

The American Association of Neurological Surgeons-Congress of Neurological Surgeons ("AANS" and "CNS"), representing over 5,200 neurosurgeons, are the two largest nonprofit scientific and educational associations for neurosurgical professionals in the world. The AANS and CNS are dedicated to excellence in neurosurgical education to advance patient care.

The American College of Obstetricians and Gynecologists is a private, voluntary, not-for-profit organization of physicians who specialize in obstetric and gynecologic care. Founded in 1951, its more than 39,000 members represent approximately 90 percent of all obstetricians and gynecologists practicing in the United States.

The American College of Physicians-American Society of Internal Medicine is a nonprofit professional society, whose membership consists of over 115,000 physicians specializing in internal medicine, the largest medical specialty group.

The American Society of Cataract and Refractive Surgery ("ASCRS"), is a nonprofit organization, the membership of which consists of nearly 8,000 physicians specializing in cataract and refractive surgery. ASCRS is dedicated to promoting the advancement of clinical practice, education, and research in cataract and refractive surgery.

The Association of American Medical Colleges ("AAMC") is a national association of medical schools, hospitals, and physician practice groups that employ teaching physicians. Located in Washington, D.C., the AAMC it is actively involved in the development of national policy affecting payment to teaching physicians and hospitals.

The Illinois State Medical Society ("ISMS") is a voluntary professional association representing 12,000

physicians, residents and medical students in Illinois. ISMS membership includes practicing physicians from a broad range of specialties, geographic locations, and types of practice.

The Medicare Act, 42 U.S.C. § 1395 *et seq.*, establishes a federally subsidized health insurance program for the elderly and disabled that is administered by petitioner, the Secretary of Health and Human Services ("Secretary"). Medicare Part A, *id.* § 1395c *et seq.*, provides insurance for the cost of hospital and related post-hospital services, including skilled nursing care. Part B, *id.* § 1395j, *et seq.*, by contrast, provides a voluntary supplemental insurance program that covers physicians' charges and other medical services.² The overwhelming majority of *amici's* physician members receive reimbursement for medical treatment and services provided to patients enrolled in Part B of the Medicare Act. Physicians can agree to accept assignment of their patients' Medicare Part B claims and then seek reimbursement directly from Medicare. *Id.* §§ 1395u(h)(1) & (b)(3)(B)(ii), 1395l(a)(1). Physicians who do not accept assignment are paid directly by their patients, who in turn seek reimbursement from Medicare.

In their capacity as assignees of their patients' Medicare claims, *amici's* physician members have the right to administrative and judicial review of reimbursement denials. 42 C.F.R. § 405.801(a). Likewise, hospitals and other providers can seek administrative and judicial review for their claims under Part A. 42 U.S.C. §§ 1395oo(b)-(g); 42 C.F.R. § 405.801, *et seq.* Subsumed within the right to judicial review of claims under Parts A and B is, of course, an

²Under Part C, beneficiaries obtain medical care through, among other options, managed care organizations that contract with Medicare. Balanced Budget Act of 1997, Pub. L. No. 105-33, Tit. IV, § 4001, 111 Stat. 276-327.

entitlement to challenge the validity of the Secretary's policies governing Medicare benefits reimbursement. Representing their members' shared interests, *amici* and other healthcare associations frequently bring challenges to Medicare rules and regulations that are of broad significance to the administration of the Medicare program. *See infra* n.18. Because individual doctors and patients may be ill-equipped to bring such challenges themselves, *amici* and other healthcare associations perform a critical function in ensuring that the Secretary's implementation of the Medicare program does not run afoul of the dictates of Congress or the Constitution.

Although this case involves a challenge to the Secretary's rules governing nursing homes' compliance with Medicare's health, safety, and quality-of-care requirements, it presents a fundamental question of district court jurisdiction over challenges to generally applicable rules and regulations in the Medicare program, including those governing the payment of benefits under Parts A and B. As a result of their role in bringing challenges to the Secretary's rules and regulations affecting benefits payment under Parts B, *amici* offer a unique perspective on the issues presented here.

At stake is the right of patients, physicians, and other providers to obtain timely and effective review of the Secretary's regulations and policies. The Secretary's position, moreover, poses a substantial threat to *amici*'s and other healthcare associations' ability to obtain *any* judicial review of challenges to the Secretary's Medicare regulations. Because *amici* and other associations of providers may not bring a claim in the administrative review process, they cannot directly avail themselves of the Medicare Act's review provisions, and *must* rely on the general federal-question jurisdiction statute to initiate a challenge to the validity of the

Secretary's policies. Taken to its extreme, the Secretary's argument here would foreclose that option entirely.

STATEMENT

This case calls upon the Court to revisit the framework established in *Bowen v. Michigan Academy of Family Physicians*, 476 U.S. 667 (1986), for determining when federal courts may exercise their general federal-question jurisdiction under 28 U.S.C. § 1331 to entertain constitutional and statutory challenges to the validity of the Secretary's Medicare rules and regulations. *Michigan Academy* held that broad-based legal challenges to the Secretary's rules and regulations, *e.g.*, the Secretary's methodology for determining benefits under Parts A and B, could be filed directly in district court under 28 U.S.C. § 1331. Conversely, the Court concluded that challenges to the application of those regulations, *e.g.*, individualized determinations as to the *amount* of benefits payable, are subject to the review provisions contained in the Medicare Act, and hence must first be channeled through the agency's review process. This case presents an opportunity to confirm the continuing vitality of *Michigan Academy*'s "amount/methodology" distinction.

Respondent challenges the Secretary's rules governing nursing homes' participation in Medicare Part A. The Secretary contends that respondent's challenge is foreclosed by the administrative and judicial review procedures of 42 U.S.C. §§ 1395cc(h) and 1395ii. It is *amici*'s position that the court of appeals correctly held that these provisions do not preclude pre-enforcement judicial review of respondent's challenge under 28 U.S.C. § 1331. Rather than dealing with the direct reviewability of nursing home regulations, however, *amici* will focus more generally on the basic *Michigan Academy* distinction between challenges to individualized determinations, which must brought through

established administrative channels, and broad-based challenges to the Secretary's rules and regulations governing such determinations, which may be brought directly in district court. For the reasons stated here, that distinction remains the law and should provide the foundation for resolving this case.

The *Michigan Academy* amount/methodology distinction stems from the interplay of several statutory provisions. Section 1395ff of the Medicare Act addresses challenges to the Secretary's determinations of the amount of benefits under Parts A and B.³ Section 1395ff has always provided judicial review procedures for Part A benefits claims; however, prior to January 1, 1987, it provided no judicial

³Section 1395ff states in relevant part:

(a) Entitlement to and amount of benefits

The determination of whether an individual is entitled to benefits under part A or part B of this subchapter, and the determination of the amount of benefits under part A or part B of this subchapter, and any other determination with respect to a claim for benefits under part A of this subchapter or a claim for benefits with respect to home health services under part B of this subchapter shall be made by the Secretary in accordance with regulations prescribed by him.

(b) Appeal by individuals; provider representation of beneficiaries

(1) Any individual dissatisfied with any determination under subsection (a) of this section as to * * *

(C) the amount of benefits under part A or part B of this subchapter (including a determination where such amount is determined to be zero)

* * *

shall be entitled to a hearing thereon by the Secretary to the same extent as is provided in section 405(b) of this title and to judicial review of the Secretary's final decision after such a hearing as is provided in section 405(g) of this title * * *.

review for disputes concerning the amount of Part B benefits, and no administrative review beyond a hearing by private insurance carriers with whom the Secretary contracts to evaluate Part B claims. 42 U.S.C. § 1395u. Congress amended § 1395ff in 1986, Omnibus Budget Reconciliation Act of 1986, Pub. L. No. 99-509, § 9341(a)(1)(B), 100 Stat. 203 ("1986 Amendments"), to provide judicial review and additional administrative review of Part B benefit determinations. As a result of these amendments, Part B benefits determinations are now subject to a five-part administrative review process and judicial review.⁴ Disputes concerning the payment of benefits under Part A proceed along a separate, four-stage administrative appeals process within the Department of Health and Human Services and judicial review.⁵ As the Secretary concedes, all of the decisionmakers in the Part A and B administrative appeals

⁴After receiving notice from an insurance carrier of a complete or partial denial of a Part B claim, dissatisfied beneficiaries or physicians with claims totaling at least \$500 (or at least \$100 for home health claims) may seek reconsideration by the carrier. 42 U.S.C. § 1395ff(b)(2)(B); 42 C.F.R. § 405.800, *et seq.* The next step in the administrative appeals process is a "fair hearing" before the carrier, 42 C.F.R. § 405.820, followed by a hearing before an administrative law judge ("ALJ"), and finally, an appeal to the Departmental Appeals Board. 42 U.S.C. § 1395ff(b)(2)(B).

⁵Under Part A, the Secretary contracts with fiscal intermediaries (generally insurance companies), which determine whether a particular medical expense is covered by Part A and, if so, the amount of reimbursement Medicare will provide. 42 U.S.C. § 1395h. A claimant dissatisfied with the intermediary's decision can seek reconsideration by the Health Care Financing Administration. If a dispute meets the threshold amount-in-controversy requirements, the claimant may then seek a hearing before an ALJ. *Id.* § 1395ff(b)(1)(C) & (b)(2). If the claim is denied, the claimant may proceed to the Appeals Council. 42 C.F.R. §§ 405.701(c), 405.724. A claimant who receives an adverse ruling from the Appeals Council may seek review in district court for claims of at least \$1,000. 42 U.S.C. § 1395ff(b)(1) & (2)(B).

processes are bound to apply the Medicare Act and the Secretary's regulations and may not address challenges to their validity. *See Pet. Br.* at 44-45.

Congress has incorporated the hearing and judicial review provisions of the Social Security program, 42 U.S.C. §§ 405 (b) and (g), into the Medicare program via 42 U.S.C. §§ 1395ff and 1395cc(h), and various other provisions of the Medicare Act. *See, e.g., id.* §§ 1320a-7(f), 1395mm(c)(5)(B), 1395w-22(g)(5). Section 405(b) entitles an individual dissatisfied with an administrative determination to "notice and an opportunity for a hearing with respect to" the determination. *Id.* § 405(b). Section 405(g) authorizes "an individual" to file an action in district court within 60 days of a "final decision" issued following a "hearing to which he was a party." 42 U.S.C. § 405(g).⁶

Congress also incorporated the Social Security Act's requirements concerning exhaustion of administrative remedies and limitations on judicial review under 42 U.S.C. § 405(h) into the Medicare Act in § 42 U.S.C. § 1395ii.⁷

⁶Section 405(g) provides in relevant part:

Any individual, after any final decision of the [Secretary] made after a hearing to which he was a party, irrespective of the amount in controversy, may obtain a review of such decision by a civil action . . . [in] district court[.] * * * The court shall have the power to enter, upon the pleadings and transcript of the record, a judgment affirming, modifying, or reversing the decision of the [Secretary], with or without remanding the cause for a rehearing.

⁷Section 1395ii provides:

The provisions of sections 406 and 416(j) of this title, and of subsections (a), (d), (e), (h), (i), (j), (k), and (l) of section 405 of this title, shall also apply with respect to this subchapter to the same extent as they are applicable with respect to [Social Security cases], except

Section 405(h), by its terms, restricts only judicial review of actions "to recover on" claims eligible for review under Parts A and B, namely individual benefit determinations.⁸ Likewise, § 405(h) applies only to "decision[s] of the [Secretary]," which, as the Secretary has acknowledged, do not include the Secretary's regulations. *See Pet. Br.* at 41 n.22.

SUMMARY OF ARGUMENT

The Court should reaffirm *Michigan Academy*'s holding that challenges to the validity of the Secretary's policies affecting Medicare benefits determinations can be brought directly in district court under 28 U.S.C. § 1331, whereas challenges to the Secretary's individual administrative determinations are subject to the Medicare Act's presentment and exhaustion requirements. That authoritative construction was not disturbed when Congress added judicial review of Part B amount determinations under § 1395ff(b)(1)(C) in 1986. While the Secretary contends this amendment rendered *Michigan Academy* a dead letter months after it was issued, she has failed to point to anything in the text or legislative

that in applying such provisions with respect to this subchapter, any reference therein to the Commissioner of Social Security or the Social Security Administration shall be considered a reference to the Secretary or the Department of Health and Human Services, respectively.

⁸Section 405(h) provides:

The findings and decision of the [Secretary] after a hearing shall be binding upon all individuals who were parties to such hearing. No findings of fact or decision of the [Secretary] shall be reviewed by any person, tribunal, or governmental agency except as herein provided. No action against the United States, the [Secretary], or any officer or employee thereof shall be brought under section 1331 or 1346 of title 28 to recover on any claim arising under this subchapter.

history of this amendment remotely suggesting that Congress intended to "overrule" *Michigan Academy*.

To the contrary, it is apparent that Congress' intent in 1986 was enhancing, not creating barriers to, judicial review under Part B. The Secretary's argument that, following the 1986 Amendments, *all* Medicare cases must first be routed through the administrative process would serve only to frustrate that clear intent. Indeed, because in 1986 Congress chose not to amend § 405(h) as incorporated by § 1395ii, the statutory provisions on which the Secretary primarily relies are the same now as when *Michigan Academy* was decided. The meaning of a statutory provision cannot change, of course, unless *Congress* revises it. And, where, as here, Congress has amended a related provision (§ 1395ff) while leaving the critical language in §§ 405(h) and 1395ii untouched, inferring such an intent would be especially inappropriate.

In addition, as the court of appeals has further explained, if something significant happened in 1986, "the point has been lost" on this Court, Pet. App. at 5a, which relied heavily on *Michigan Academy*'s distinction between individualized adjudication and broad legal challenges to regulatory action in *McNary v. Haitian Refugee Center, Inc.*, 498 U.S. 479 (1991), which concerned the availability of judicial review in immigration proceedings. In fact, the *McNary* Court not only affirmed *Michigan Academy*'s holding, it extended its reasoning outside the Medicare context and broadened the applicability of the presumption of judicial review to situations in which no *meaningful* judicial review is provided.

In any event, the presumption of judicial review, while still applicable after the 1986 Amendments, was not the sole basis for the Court's ruling in *Michigan Academy*. The Court's decision was primarily grounded in the text of the statute, and the relevant language is unchanged. Likewise,

the addition of judicial review for Part B "amount" disputes in the 1986 Amendments did not, as the Secretary asserts, create an "irreconcilable conflict" between *Michigan Academy* and *Heckler v. Ringer*, 466 U.S. 602 (1984). Pet. Br. at 34. Not only did *Ringer*, in contrast to *Michigan Academy*, involve individual claims for benefits, the Court in *Michigan Academy* also expressly indicated that its reasoning applied to Part A and Part B benefits alike.

Finally, the Secretary's contention that broad-based challenges to her policies must be funneled through an administrative process where legal challenges cannot be adjudicated, factual findings and the compilation of an administrative record are unnecessary, and there is no agency expertise to apply is at odds with well-settled principles of administrative law, judicial economy, and associational representation. Pursuant to such principles, where exhaustion of an administrative process would be futile, as it undoubtedly would be here, courts routinely allow litigants to bring their claims directly in district court. The reasons for doing so are particularly compelling where, as here, doing so will establish at the outset the validity of the applicable legal standard for the numerous individual claims that will be adjudicated in administrative appeals. By allowing broad challenges to the Secretary's rules and regulations to proceed directly to district court, courts can avoid resolving legal challenges on a piecemeal basis as they percolate through the administrative review process.

The Secretary's argument would jeopardize *amici*'s and other health care associations' ability to bring broad-based challenges to the validity of the Secretary's regulations and policies. Because associations cannot file a claim for benefits, they cannot avail themselves of the review provisions of the Medicare Act. If, as the Secretary contends, they are confined by those jurisdictional provisions, they

would never be able to initiate an action contesting the Secretary's policies. That position would clearly conflict with the presumption of judicial review on which the Secretary so heavily relies.

ARGUMENT

I. MICHIGAN ACADEMY CONTINUES TO PERMIT JUDICIAL REVIEW UNDER 28 U.S.C. § 1331 OF FACIAL CHALLENGES TO MEDICARE RULES AND REGULATIONS.

Bowen v. Michigan Academy of Family Physicians, 476 U.S. 667 (1986), sets forth the appropriate framework for determining the availability of judicial review under 28 U.S.C. § 1331 in this and other Medicare Act cases. Because the Medicare Act does not establish procedures for judicial review of challenges to the validity of the Secretary's regulations and instructions affecting benefits payments -- i.e., challenges to the "methodology" for calculating Medicare benefits -- a plaintiff may bring such a challenge in district court under the general federal-question jurisdiction statute, 28 U.S.C. § 1331. Conversely, because Congress has provided administrative and judicial review of individual benefit determinations under the Medicare Act, those procedures are exclusive with respect to such determinations.

A. Michigan Academy Was Grounded In The Text And Legislative History Of The Medicare Act.

In *Michigan Academy*, an association of family physicians and several individual doctors challenged a regulation promulgated under Medicare Part B authorizing payments of different amounts for similar services. 476 U.S. at 668. Just a few years before deciding *Michigan Academy*, the Court had held that Congress had limited review of determinations of the amount of Part B benefits to the "fair

hearing by the carrier" provided in 42 U.S.C. § 1395u(b)(3)(C). See *United States v. Erika, Inc.*, 456 U.S. 201 (1982). Because Part B awards were "substantially smaller" and more numerous than Part A awards, *id.* at 208 n.11 (quoting S. Rep. No. 89-404, at 54-55 (1965)), judicial review of such awards risked "overloading the courts with trivial matters," which Congress sought to avoid. *Id.* at 210 n.13 (citations and internal quotations omitted).

Michigan Academy nevertheless held that broad-based statutory and constitutional challenges to the regulations governing Part B determinations were subject to judicial review under 28 U.S.C. § 1331. It rejected the contention that § 1395ff impliedly foreclosed judicial review of methodology challenges under 28 U.S.C. § 1331. Noting that administrative procedures were provided in Parts A and B for challenging individual determinations of "amounts" of benefits to be paid, the Court held that § 1395ff "does not speak to challenges mounted against the *method* by which such amounts are to be determined rather than the *determinations themselves*." *Michigan Academy*, 476 U.S. at 675. (emphasis added)⁹ Because "an attack on the validity of a regulation is not the kind of administrative action that we described in *Erika* as an 'amount determination,'" the Court concluded that it was not covered by § 1395ff, and was consequently exempt from the judicial review provisions of § 405(g), which § 1395ff incorporated by reference. *Id.* at 676. That such legal challenges could not be entertained in the administrative appeals process further confirmed that

⁹Although the plaintiffs in *Michigan Academy* challenged a regulation under Part B, the Court reasoned that, by their terms, the review provisions for Part B (§ 1395u(b)(3)(C)) and the review provision for Part A (§ 1395ff(b)(1)(C)) applied only to challenges disputing the "amount" of benefits due. See 476 U.S. at 675 (referring to the separate review provisions of both Parts A and B); see also *infra* at page 22.

Congress did not intend to bar their direct review under 28 U.S.C. § 1331. *See id.* at 678.

The Court found this conclusion perfectly consistent with the text and legislative history of § 1395ii, which incorporates § 405(h), and on which the Secretary had relied. It had previously held that the first two sentences of § 405(h), which limit the review available for any “final decision” of the Secretary “made after a hearing,” required exhaustion of administrative remedies. *Weinberger v. Salfi*, 422 U.S. 749, 757 (1975) But *Michigan Academy* clarified that this exhaustion requirement did not apply to challenges to the validity of the Secretary’s regulations, for which there was no administrative hearing available. *See* 476 U.S. at 679 n.8. The Court also rejected the notion that a regulation was a “decision of the Secretary,” which is defined as a determination made by the Secretary “*after a hearing*.” 42 U.S.C. §§ 405(g) & (h) (emphasis added).

Section 405(h)’s third sentence bars all “actions” against the government under 28 U.S.C. § 1331 to “recover on any claim arising under” the Medicare Act. *Michigan Academy* found that this provision precludes review only of amount determinations — “i.e., those ‘quite minor matters’ remitted finally and exclusively to adjudication by private insurance carriers in a ‘fair hearing.’” 476 U.S. at 680 (internal citation omitted). In addition, as the court of appeals explained, a challenge to the validity of a regulation governing the method for calculating benefits is “not an action to ‘recover on’ a claim, even when per *Salfi* a constitutional objection to the regulation is a ‘claim arising under this subchapter.’” Pet. App. at 6a (emphasis added). This restriction applies only to an individual demand for benefits.

In sum, the Court found that §§ 1395ff and 1395ii worked in tandem: for matters covered by § 1395ff (*i.e.*, amount determinations under Parts A and B), § 1395ii limited

the availability of judicial review; as for matters falling outside of § 1395ff, § 1395ii did not apply, and hence they could be reviewed under a district court’s general federal-question jurisdiction. *See* 476 U.S. at 679-80.

B. *Michigan Academy* Was Not “Overruled” By The 1986 Amendments.

The Secretary and several courts of appeals¹⁰ have mistakenly concluded that Congress “overruled” *Michigan Academy* in 1986, months after it was decided, by adding judicial review procedures for Part B “amount” determinations in § 1395ff(b)(1)(C). While the Secretary has seized upon this amendment as a basis for discarding *Michigan Academy*, there is, in fact, nothing that suggests that Congress intended to overturn that ruling.

If, as the Secretary asserts, Congress had sought to overrule *Michigan Academy*, it surely would have mentioned this objective in the legislative history. Yet the committee reports discussing the amendments to § 1395ff, drafted a year before this Court’s decision, contain none. *See H.R. Rep. No. 99-727 95* (1986), reprinted in 1986 U.S.C.C.A.N. 3607, 3685; H.R. Conf. Rep. No. 99-1012 351 (1986), reprinted in 1986 U.S.C.C.A.N. 3868, 3996. Far from repudiating *Michigan Academy*, the principal sponsor of the amendment to § 1395ff(b)(1)(C) stated that “[t]his legislation strengthens the rights established by the Supreme Court in its decision *Bowen* versus *Michigan Academy* of Family Physicians, earlier this year.” 132 Cong. Rec. 32978 (1986) (statement of Rep. Wyden) (emphasis added). Congress’ expansion of judicial review rights for Part B amount disputes is an odd

¹⁰See, e.g., *Michigan Ass’n of Homes & Servs. for the Aging v. Shalala*, 127 F.3d 496, 501 (6th Cir. 1997); *St. Francis Med. Ctr. v. Shalala*, 32 F.3d 805, 812 (3d Cir. 1994); *National Kidney Patients Ass’n v. Sullivan*, 958 F.2d 1127, 1133 (D.C. Cir. 1992).

basis for inferring an intent to create new *limitations* on judicial review for Part B methodology claims.

The Secretary's interpretation of the 1986 Amendments also ignores Congress' original purpose in foreclosing judicial review for Part B amount disputes, a decision the 1986 Amendments were intended to undo. As the Court explained in *Erika*, Congress had precluded judicial review of relatively "trivial" Part B claims in order to prevent them from taxing the federal court system. 456 U.S. at 210; see also *id.* at 208-11. That bar on judicial review, however, extended only to "matters *solely* involving *amounts* of benefits under Part B." *Id.* at 210 (quoting H.R. Conf. Rep. No. 92-1605 at 61 (1972)) (emphasis added). Just as Congress had intended to preclude judicial review of Part B amount disputes only, so, too, it amended § 1395ff in 1986 with the clear purpose of adding judicial review procedures solely for such claims. See H. Rep. No. 99-727 at 95, reprinted in 1986 U.S.C.C.A.N. at 3685. Nothing suggests that it intended these amendments to foreclose review of Part B methodology disputes under 28 U.S.C. § 1331.¹¹

Nor is such an intent implicit in the amendments themselves. There is simply "no conflict between the decision in *Michigan Academy* and Congress' subsequent grant of jurisdiction to review certain Medicare Part B determinations in the 1986 Act." *Griffith v. Bowen*,

¹¹The Secretary points to a statement in a 1965 Senate Report that the "remedies provided by these review procedures shall be exclusive." Pet. Br. at 33 (quoting S. Rep. No. 89-404 55 (1965)). But that statement hardly supports the Secretary's argument that Congress adopted the 1986 Amendments as a rejection of *Michigan Academy*. As the Court made clear in *Erika*, the statement simply reflects Congress' intent to bar other types of judicial review of matters covered by the review provisions provided in the Medicare Act, e.g., disputes concerning the amount of Part B awards. See 456 U.S. at 208 n.11.

678 F. Supp. 942, 945 (D. Mass. 1988). *Accord Abbott Radiology Assocs. v. Sullivan*, 801 F. Supp. 1012, 1017-18 (W.D.N.Y. 1992) (by providing expanded review for Part B "amount" determinations, because Congress "did not touch upon challenges by individuals to the Secretary's regulations . . . the 1986 amendments did not displace the reasoning of *Michigan Academy*"). Rather, as they did before the 1986 Amendments, disputes concerning Part B "amount" determinations and broad challenges to the Secretary's regulations proceed on different tracks: for the former, judicial review is subject to the Medicare Act's presentment and exhaustion requirements, 42 U.S.C. §§ 1395ff, 405(g) and (h); the latter cannot be considered in the administrative appeals process, but may be brought in district court under 28 U.S.C. § 1331.

C. *McNary Affirmed Michigan Academy's Reasoning And Expanded The Presumption Of Judicial Review.*

As the court of appeals observed, "if something important happened in 1986, the point has been lost on the Supreme Court, which in 1991 [in *McNary v. Haitian Refugee Ctr., Inc.*, 498 U.S. 479], reiterated its conclusion that § 1395ii does not affect regulatory challenges that are detached from any request for reimbursement." Pet. App. at 6a. See also *Reno v. Catholic Social Servs., Inc.*, 509 U.S. 43 (1993) (holding district court had jurisdiction over pre-enforcement challenge to immigration regulation under *McNary*). In fact, *McNary* went beyond *Michigan Academy*, extending its reasoning outside the Medicare context and expanding the applicability of the presumption of judicial review.

McNary involved a constitutional challenge to the Immigration and Naturalization Service's ("INS") procedures for granting amnesty applications under the Immigration

Reform and Control Act of 1986 (“IRCA”), Pub. L. No. 99-603, 100 Stat. 3359. As it had in *Michigan Academy*, the government argued that such a challenge could be raised only pursuant to IRCA’s judicial review provisions, and that statutory language limiting judicial review of “a determination respecting an [amnesty] application” to deportation or exclusion proceedings barred jurisdiction under 28 U.S.C. § 1331 over other challenges. 498 U.S. at 490-500.

Relying extensively on *Michigan Academy*, the Court dismissed these contentions. *See id.* at 497-98. In noting that its decision in *McNary* was “supported by our unanimous holding in *Bowen [v. Michigan Academy]*,” the Court affirmed the “critical” distinction between “an individual ‘amount’ determination” and a dispute concerning “the procedures for making such determinations.” *Id.* Because IRCA’s limitations on judicial review applied by their terms to a “determination respecting an application” for amnesty, 8 U.S.C. § 1160(e)(1) (emphasis added), the Court concluded they covered only *individual* amnesty applications, not “general collateral challenges to unconstitutional practices and policies used by the agency in processing applications.” 498 U.S. at 492. Accordingly, Congress had not precluded direct judicial review of broad constitutional challenges under 28 U.S.C. § 1331 even though review of disputes over *individual* amnesty determinations was confined to IRCA’s administrative and judicial review provisions. *See id.*

Although IRCA provided for some judicial review (in the context of a deportation or exclusion hearing), the Court found the presumption that Congress intends administrative rulemaking to be subject to judicial review to apply. *See id.* at 496. It made clear that the critical question is not, as the Secretary asserts, whether the statute affords any judicial review, no matter how delayed, Pet. Br. at 31-32, but whether

“as a *practical* matter” the statute offers “*meaningful* judicial review” of a collateral legal challenge. 498 U.S. at 496 (emphasis added). If the obstacles to judicial review are sufficiently substantial, it is the “practical equivalent of a total denial of judicial review,” and the government must present “clear and convincing evidence” that Congress intended to bar judicial review under 28 U.S.C. § 1331. *Id.* at 497.

McNary’s expansion of the presumption of review rebuts the Secretary’s contention that the 1986 Amendments, by providing some form of judicial review for Part B benefit claims, albeit delayed, removed the sole basis for the Court’s decision. *See Pet. Br.* at 31-32. Requiring individual physicians and beneficiaries, whose claims may be of relatively small dollar value, to proceed through a lengthy and ultimately futile administrative appeal is tantamount to an outright denial of meaningful judicial review for collateral constitutional and statutory challenges.¹² Thus, even if *Michigan Academy* had been decided after the 1986 Amendments, the presumption of review would still have applied, and the Court would still have required clear and convincing evidence that Congress intended to foreclose review of Part B methodology challenges. But the legislative history of the 1986 Amendments does not vaguely suggest such an intent, let alone offer the type of evidence necessary to satisfy this rigorous standard. *See supra* pages 15-17.

¹²With respect to a trade or professional association, the issue is more than the *de facto* denial of judicial review. As discussed more fully below, *see infra* at pages 28-30, an association cannot file a claim for benefits in the administrative appeals process or initiate an action in district court under the Medicare Act’s judicial review procedures in § 405(g). Consequently, an association would -- apart from the possibility of intervening in a lawsuit -- be precluded from obtaining *any* judicial review of the Secretary’s rules and regulations.

In any event, the key to the Court's decision in *Michigan Academy* was that §§ 1395ff and 1395ii, by their terms, did not purport to address broad-based challenges to the Secretary's rules and regulations. Congress' addition of judicial review for Part B "amount" disputes in 1986 did not alter the fact that § 1395ff addresses only review of amount determinations and "simply does not speak" to challenges to the validity of the Secretary's regulations. *Michigan Academy*, 476 U.S. at 675. Congress, moreover, left the language of § 1395ii as well as the text of §§ 405(g) and (h), which § 1395ii incorporates, substantively untouched.

It is simply incorrect to suggest that *Michigan Academy* interpreted § 1395ii to bar judicial review of all claims arising under the Medicare Act, but, because of the presumption of judicial review, chose not to enforce that restriction where the Secretary's methodology was challenged. *Michigan Academy* did not create an "exception" to § 1395ii or § 1395ff based on the presumption of judicial review. Pet. App. at 6a. Nor could it, because "[t]he presumption of judicial review is, after all, a presumption" to which "Congress can, of course, make exceptions." 476 U.S. at 672-73. Cf. *Bank of Nova Scotia v. United States*, 487 U.S. 250, 254 (1988) (court's exercise of supervisory power may not conflict with statute). Rather, it was the text of § 1395ii, which "read in light of its 1972 legislative history, affects only 'amount determinations,'" that was dispositive. Pet. App. at 6a. Because "[n]either th[e] critical language from § 405(h) nor the history of § 1395ii changed in 1986," *Michigan Academy*'s interpretation of those provisions retains its vitality. *Id.*

In addition, *McNary*'s reliance on *Michigan Academy* leaves no doubt that *Michigan Academy* is not limited to the specific context in which it arose, or even limited to the Medicare Act. Although the amount/methodology distinction

does not apply to immigration cases, this Court invoked *Michigan Academy*'s more fundamental distinction between individualized administrative determinations and legal challenges to the rules governing those determinations. See *McNary*, 498 U.S. at 491-92. Thus, even if, as the Secretary asserts, the amount/methodology distinction "has no logical place" here, Pet. Br. at 33, there clearly is a distinction for reviewability purposes between an individualized determination that a nursing does not satisfy the standards for Medicare participation, 42 U.S.C. § 1395cc(h), and a facial legal challenge to the Secretary's rules and regulations affecting such a determination. Likewise, the distinction between individualized determinations and collateral legal challenges is equally germane to other Medicare cases, such those involving civil monetary penalties for specified statutory violations, 42 U.S.C. § 1320a-7a, the Medicare Act's anti-fraud provisions, *id.* § 1320a-7b, and the financial disclosure requirements for providers under Part B. *Id.* § 1320a-3a.

D. The Court Of Appeals' Decision Is Consistent With *Ringer*.

The court of appeals' decision is perfectly consistent with *Heckler v. Ringer*, 466 U.S. 602 (1984), which did not even address the amount/methodology distinction subsequently articulated in *Michigan Academy*. *Ringer* required administrative exhaustion prior to a judicial challenge by Part A claimants seeking coverage for a surgical procedure that the Secretary had disallowed. Distinguishing between the two types of claimants involved in the case -- three of whom had undergone the surgery and the fourth who had not -- the Court concluded that neither group could proceed directly to district court. The Secretary has argued that the only basis for distinguishing *Michigan Academy* from *Ringer* is that the Medicare Act did not provide judicial

review of the Part B claims at issue in *Michigan Academy*, but did for the Part A claims at issue in *Ringer*. Pet. Br. at 29-34. Thus, the Secretary asserts, the 1986 Amendments *must* be read to overturn *Michigan Academy* to avoid an “irreconcilable conflict” between *Ringer* and *Michigan Academy*. See Pet. Br. at 34. This argument fails for several reasons.

As a threshold matter, the Secretary’s argument rests on the mistaken premise that *Michigan Academy* would have been decided differently had the specific claim at issue arisen under Part A (as *Ringer* did) rather than Part B. While *Michigan Academy* did involve a Part B claim, the Court reasoned that both the Part B provision at issue in *Erika* (§ 1395u(b)(3)(C)), and the Part A provision at issue in *Ringer* (§ 1395ff(b)(1)(C)), applied only to challenges disputing the amount of benefits:

The reticulated statutory scheme, which carefully details the forum and limits of review of “any determination . . . of . . . the amount of benefits under part A,” 42 U.S.C. § 1395ff(b)(1)(C) (1982 ed. Supp. II), and of the “amount of . . . payment” of benefits under Part B, 42 U.S.C. § 1395u(b)(3)(C), simply does not speak to challenges mounted against the method by which such amounts are to be determined rather than the determinations themselves.

476 U.S. at 675 (emphasis added). Accordingly, *Michigan Academy* made clear that under *both* Part A and Part B, challenges to the Secretary’s methodology governing benefit awards were not subject to the exclusive review provisions of the Medicare Act.

Michigan Academy could bridge the review processes for Parts A and B notwithstanding *Ringer*, because *Ringer* did not involve the kind of broad challenge to the Secretary’s

rules and regulations raised in *Michigan Academy*. As the Court explained, *Ringer* involved individual “claims for benefits” and the “amount determinations” concerning such claims. 476 U.S. 667 n.7. Likewise, the Court found that *Ringer* was not controlling in *McNary* because the “essence” of the former case was a “claim of entitlement to payment for [a] surgical procedure.” *McNary*, 498 U.S. at 494. As to the claims brought by the plaintiffs who had already had the procedure, *Ringer* itself held that they were “at bottom” nothing more than “claim[s] that they should be paid for their . . . surgery.” *Ringer*, 466 U.S. at 614. To the extent they contested the validity of the Secretary’s policies, their legal challenges were “inextricably intertwined” with [their] claims for benefits.” *Id.* (citations omitted). In addition, the administrative review process was “in no sense futile” because, with respect to these plaintiffs, ALJs were not bound by the regulation at issue and hence authorized to award the reimbursement they sought. *Id.* at 619.¹³

As for the plaintiff who had not had the surgery, the Court determined that his claim was also “essentially one requesting the payment of benefits and hence cognizable only under § 405(g).” *Id.* at 620. *See also id.* at 608 n.4 (characterizing all four *Ringer* plaintiffs’ claims “essentially as claims for benefits”); *McNary*, 498 U.S. at 494-95 (discussing *Ringer*). Although he had no immediate claim to exhaust, that fact meant only that his challenge was

¹³In *Ringer*, the Secretary’s regulations barring reimbursement for the surgery in question did not apply to individuals who had the surgery in reliance on prior ALJ rulings awarding such reimbursement. *Id.*

premature, not that the federal courts had jurisdiction to issue "advisory opinions." *Ringer*, 466 U.S. at 621-22.¹⁴

II. MICHIGAN ACADEMY COMPORTS WITH WELL-ESTABLISHED PRINCIPLES OF ADMINISTRATIVE LAW, JUDICIAL ECONOMY, AND ASSOCIATIONAL REPRESENTATION.

Michigan Academy's distinction between individual administrative determinations and collateral legal challenges offers a sound and workable approach for addressing the thorny jurisdictional questions so often raised by the Social Security Act and Medicare Act.¹⁵ Indeed, lower courts that have applied the *Michigan Academy* distinction have done so with relative ease, readily sorting out those challenges worthy of immediate judicial review and those where exhaustion of administrative remedies was appropriate. See, e.g., *Cosgrove*, 999 F.2d at 632; *McCuin v. Secretary of Health & Human Servs.*, 817 F.2d 161, 163-66 (1st Cir. 1987); *Kuritzky v. Blue Shield*, 850 F.2d 126, 128 (2d Cir. 1988); *Medical Fund-Philadelphia Geriatric Ctr. v. Heckler*, 804 F.2d 33 (3d Cir. 1986); *Mediplex, Inc. v. Shalala*, 39 F. Supp.2d 88, 92-94 (D. Mass. 1999); *Stewart v. Sullivan*, 816 F. Supp. 281, 287-88 (D.N.J. 1992); *Abbott Radiology Assocs. v. Sullivan*, 801 F. Supp. 1012, 1015-18 (W.D.N.Y. 1992); *Griffith*, 678 F. Supp. at 943-45.

¹⁴Likewise, there is no "irreconcilable conflict" between *Michigan Academy* and *Salfi*. While *Salfi* involved a challenge to a provision of the Social Security Act, like *Ringer*, it was, at bottom, a simple claim for benefits. See 422 U.S. at 760-61. Consequently, the Medicare Act offered the exclusive source of district court jurisdiction.

¹⁵See, e.g., *Heckler v. Ringer*, 466 U.S. 602 (1984); *Mathews v. Eldridge*, 424 U.S. 319 (1976); *Weinberger v. Salfi*, 422 U.S. 749 (1975); *Cosgrove v. Sullivan*, 999 F.2d 630 (2d Cir. 1993).

Also, *Michigan Academy* comports with basic administrative law principles. As the Secretary acknowledges, see Pet. Br. at 18, an exhaustion requirement is designed to allow the agency to: (1) "develop the necessary factual background upon which decisions should be based," *McKart v. United States*, 395 U.S. 185, 194 (1969); (2) "compile a record which is adequate for judicial review," *Salfi*, 422 U.S. at 765; (3) give the agency a chance to exercise its expertise to the issues raised, see *McKart*, 395 U.S. at 194; and (4) allow an agency to "correct its own errors," thereby mootng the dispute. See *McCarthy v. Madigan*, 503 U.S. 140, 145 (1992).

Funneling facial legal challenges to the Secretary's regulations through the administrative process furthers none of these objectives. Contrary to the Secretary's claims, by its nature, a facial challenge to the validity of a regulation typically will not require the "development of a factual record," Pet. Br. at 18, at least not the type of record compiled in a § 405(g) hearing. Nor are such questions appropriately left to an agency's expertise, particularly since they cannot even be entertained in the administrative appeals process. And because the Secretary has already made up her mind regarding the legal questions at issue -- as embodied in the regulation challenged -- there is no realistic chance that the dispute in question will be mooted.

It is hardly "fair and sensible," as the Secretary has asserted, to require someone like respondent to go through the lengthy and necessarily futile process of administrative adjudication. Pet. Br. at 22. To the contrary, litigants are commonly excused from exhaustion where doing so would serve no legitimate objective. See *McCarthy*, 503 U.S. at 148. "Plainly," exhaustion would serve no valid purpose where the "only issue is the constitutionality of a statutory requirement, a matter which is beyond [the agency's]

jurisdiction to determine." *Salfi*, 422 U.S. at 765. Not only would such a requirement be "futile for the applicant," but it would also constitute a "commitment of administrative resources unsupported by any administrative or judicial interest." *Id.* at 765-66.

Moreover, where, as here, "inordinate delay is the hallmark of the [administrative] appeal process," Timothy J. Blanchard, "*Medical Necessity*" Denials as a Medicare Part B Cost-Containment Strategy, 34 St. Louis L.J. 939, 964 (1990), justice delayed is effectively justice denied. In 1998, for example, after the initial denial of a claim by a carrier, the process under Part B took an average of 1 year and 10 months. See Testimony of Mike Hash, Deputy Administrator, HCFA, before the House Ways & Means Subcommittee on Health, Medicare Cover Policy Determinations and Appeals (April 22, 1999) (<http://www.hcfa.gov/testimony/1999> as of 6/25/99). Part A claimants fare little better. In 1998, the administrative appeals process for Part A claims took an average of 362.9 days after initial denial by carrier. See *id.* This "unreasonable [and] indefinite timeframe," *McCarthy*, 503 U.S. at 146, will inevitably deter numerous individual claimants from pursuing their constitutional or statutory challenges.

Allowing legal challenges to be brought initially in district court also promotes judicial economy. As the Court observed in *Michigan Academy*, the "'validity of a standard can be readily established, at times even in a single case.'" 476 U.S. at 680 n.11 (internal citations omitted). Contrary to the Secretary's argument, see Pet. Br. at 22, resolving such challenges at the outset is inherently more efficient than addressing them on a piecemeal basis after numerous individual claims have wound their way through the

administrative process.¹⁶ Whether or not the regulation is upheld, a "pre-enforcement challenge" can "speed enforcement" of administrative policies. *Abbott Labs. v. Gardner*, 387 U.S. 136, 154 (1967). If the regulation is sustained, "its enforcement thereafter can be swift, efficient, and inexpensive." II Kenneth C. Davis & Richard J. Pierce, Jr., ADMINISTRATIVE LAW TREATISE § 15.14 at 376 (3d ed. 1994). Conversely, if the rule is invalidated, "the agency benefits from prompt resolution . . . [because it] then can begin immediately to pursue an alternative means of performing its statutory missions." *Id.*

In addition, resolving facial challenges outside the administrative process will not, as the Secretary contends, result in lawsuits raising abstract claims that exceed "manageable proportions." Pet. Br. at 27, 28. Basic justiciability rules, see, e.g., *Lujan v. Defenders of Wildlife*, 504 U.S. 555 (1992), will ensure that challenges to the Secretary's policies are sufficiently concrete and ripe to be heard in district court. See *Reno v. Catholic Social Servs., Inc.*, 509 U.S. 43 (1993) (dismissing pre-enforcement challenge to immigration regulation as unripe). This case itself is proof of that principle: having determined the district court had jurisdiction, the court of appeals nonetheless declined to reach respondents' claim on the ground that it was premature. Pet. App. at 10a-11a.¹⁷ See also *Stewart*,

¹⁶Nor will such review "open the floodgates" to millions of Medicare claims. Dismissing any such concern in *Michigan Academy*, the Court explained that, "[u]nlike the determination of the amounts of benefits," a challenge to the method by which such amounts are calculated "ordinarily affects vast sums of money and thus differs qualitatively" from a dispute over the amount of benefits due. 476 U.S. at 680 n.11.

¹⁷The court of appeals also remanded to the district court to determine whether respondent's due process challenge was ripe. Pet. App. at 12a.

816 F. Supp. at 287-91 (dismissing pre-enforcement challenge to Secretary's policies as unripe).

The *Michigan Academy* distinction is also consonant with the basic structure of the APA, 5 U.S.C. § 551, *et seq.*, which separates an agency's adjudication of individual matters, *id.* § 554, and its establishment of generally applicable policies through rulemaking. *Id.* § 553. See generally Martin Shapiro, *Administrative Discretion: The Next Stage*, 92 Yale L.J. 1487, 1488 (1983) ("[t]he APA essentially divides administrative action into three parts: quasi-judicial adjudication; quasi-legislative rulemaking; and a residual category . . . [of] 'informal action'"); David L. Shapiro, *The Choice of Rulemaking or Adjudication in the Development of Administrative Policy*, 78 HARV. L. REV. 921 (1965).

In this case, the Secretary seeks to collapse the two, effectively barring challenges under the APA's rulemaking requirements unless they can be raised along with an individual claim for benefits. But, by its very nature, a challenge to the Secretary's compliance with the APA, e.g., its notice and comment rules, should be able to be raised outside the context of an individual dispute. The notice and comment rules serve broad purposes, and the right to receive notice of a proposed rulemaking and to submit comments does not belong solely to individuals who ultimately challenge the application of the agency's rule. Eliminating APA challenges other than those that can be brought in conjunction with an individual administrative claim would seriously limit the right to bring such a challenge, thereby substantially insulating the Secretary's regulations from review.

The Secretary's position would also jeopardize *amici's* and other associations' ability to challenge the legality of the Secretary's Medicare rules and regulations directly affecting

their members. Under Part B, for example, the claimants often are not hospitals or other institutions, but individual beneficiaries and healthcare providers. These individuals are far less suited to bring broad legal challenges to the administration of the Medicare program than associations representing the common interests of their members. Indeed, healthcare associations have done so for years; *Michigan Academy* itself involved such a challenge.¹⁸

As respondent has noted, *see Br. in Opp.* at 3, such associations cannot file a claim for benefits in the administrative review process. But § 405(g), which the Secretary contends is the exclusive avenue for judicial review, authorizes only "an individual" to file an action in district court for review of a "final decision of the [Secretary] made after a hearing to which he was a party * * *." 42 U.S.C. § 405(g) (emphasis added). And a regulation is not a "final decision of the Secretary" under § 405(g). *See Michigan Academy*, 476 U.S. at 679 n.8. Consequently, without the ability to sue under 28 U.S.C. § 1331, an association could never challenge the Secretary's rules and regulations.¹⁹ Such a result would run counter to the "strong

¹⁸See, e.g., *American Academy of Dermatology v. Department of Health & Human Servs.*, 118 F.3d 1495 (11th Cir. 1997); *American Hosp. Ass'n v. Bowen*, 857 F.2d 267 (5th Cir. 1988); *College of Am. Pathologists v. Heckler*, 734 F.2d 859 (D.C. Cir. 1984); *American Medic. Ass'n v. Weinberger*, 522 F.2d 921 (7th Cir. 1975); *American Medic. Ass'n v. Mathews*, 429 F. Supp. 1179 (N.D. Ill. 1977); *Association of Am. Physicians & Surgeons v. Weinberger*, 395 F. Supp. 125 (N.D. Ill. May 1975).

¹⁹Associations might be able to intervene in an action under Rule 24 of the Federal Rules of Civil Procedure. However, intervention in a case following exhaustion of the administrative process is a poor alternative to bringing a facial challenge under 28 U.S.C. § 1331 because of the unreasonable delays discussed above. By the time an individual determination concerning benefit amounts finds its way to the district court,

presumption that Congress intends judicial review of administrative action," *Michigan Academy*, 476 U.S. at 670, the well-settled right of associations to bring suits on behalf of their members, *see United Food & Commercial Workers Union Local 751 v. Brown Group, Inc.*, 517 U.S. 544 (1996); and the critical role associations have played in challenging program-wide Medicare policies.²⁰

CONCLUSION

For the foregoing reasons, the Court should affirm the decision of the court of appeals.

Respectfully submitted,

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the damage done by a defective national payment rule or other regulation could be irreparable.

²⁰The Court has held that where administrative appeals will be futile, an individual who has satisfied the Medicare Act's presentment requirements may be excused from completing the administrative process. *Salfi*, 422 U.S. at 764-67. That, however, is not an option for associations, which cannot file a claim in the administrative appeals process.

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In The
Supreme Court of the United States

◆
**DONNA E. SHALALA, SECRETARY OF HEALTH
 AND HUMAN SERVICES, ET AL.,**

Petitioners,

v.

ILLINOIS COUNCIL ON LONG TERM CARE, INC.,

Respondent.

◆
**On Writ Of Certiorari
 To The United States Court Of Appeals
 For The Seventh Circuit**

◆
**BRIEF FOR THE AMERICAN HOSPITAL
 ASSOCIATION AS AMICUS CURIAE
 IN SUPPORT OF RESPONDENT
 ILLINOIS COUNCIL ON LONG TERM CARE, INC.**

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QUESTION PRESENTED

Whether 42 U.S.C. § 405(h), incorporated into the Medicare Act by 42 U.S.C. § 1395ii, eliminates jurisdiction under 28 U.S.C. §§ 1331 and 1346 over an action asserting constitutional and statutory challenges to Medicare regulations where the contentions alleged cannot be considered in the administrative review process and are collateral to an individual claim.

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INTEREST OF THE AMICUS CURIAE

The American Hospital Association ("AHA") files this *amicus curiae* brief in support of Respondent Illinois Council on Long Term Care, Inc. ("Long Term Care").¹ AHA, a not-for-profit association founded in 1898, is the primary national membership organization for hospitals and health care institutions in the United States. Its membership includes approximately 4,500 hospitals and other institutions, as well as over 35,000 personal members. AHA's mission is to advance the health of individuals and communities; the AHA leads, represents, and serves health care provider organizations that are accountable to the community and committed to health improvement.

This case asks the Court to construe the Health Care for the Aged Act, commonly known as the Medicare Act, 42 U.S.C. § 1395, *et seq.* Virtually every institutional member of AHA is a Medicare provider. Many members provide long-term care services in addition to patient acute care. The purpose behind Medicare closely tracks the mission of AHA. The purpose of Part A of the Medicare Act is to provide "basic protection against the costs of hospital, related post-hospital, home health services, and hospice care" for those persons over sixty-five, disabled over twenty-four months, or suffering from end stage renal disease. 42 U.S.C. § 1395c. The purpose of Part B is described as "a voluntary insurance program to provide

¹ AHA has obtained the written consent of the parties pursuant to Supreme Court Rule 37.2(a) and has filed copies of letters evidencing such consent together with this Brief.

Pursuant to Supreme Court Rule 37.6, AHA states that counsel for AHA authored this Brief in whole. No person or entity, other than AHA and its members, has made a monetary contribution to the preparation or submission of the Brief.

medical insurance benefits" for elderly and disabled individuals. 42 U.S.C. § 1395g. Given the similarities between the mission of AHA and the purpose of Medicare, AHA has a deeply-rooted interest in ensuring that the Medicare Act is correctly interpreted and applied.

Moreover, as participants in the Medicare program, AHA's members must comply with its regulatory standards for health, safety, and quality of patient care. AHA's members may therefore find themselves subject to enforcement measures taken by the Secretary ("Secretary") of Health and Human Services ("HHS"). If she finds a violation, the Secretary may impose civil money penalties, deny further reimbursement for treating Medicare beneficiaries, and terminate a hospital's right to participate in Medicare. Therefore, it is imperative to AHA's members that the Secretary administer the Medicare Act in a manner that is clear, fair, and faithful to the intent of Congress.

STATEMENT OF THE CASE

This case concerns whether hospitals, nursing homes, and other participants in the Medicare program may seek pre-enforcement relief in federal court from facially invalid rules and regulations promulgated under the Medicare Act, or whether they must endure a long, complex, and costly administrative review process, entirely unrelated to their constitutional and statutory claims, before doing so. The Medicare program represents a massive undertaking by the federal government. Medicare's beneficiaries number in excess of 38 million individuals, representing approximately fourteen percent of the population of the United States. Timothy S. Jost, *Governing Medicare*, 51 ADMIN. L. REV. 39, 40 (1999). Hundreds of managed care plans; thousands of hospitals, skilled nursing facilities, home health agencies, and hospices; and

hundreds of thousands of physicians and other practitioners provide health care services for these beneficiaries. *Id.* The Secretary runs the Medicare program through the Health Care Financing Administration ("HCFA"). In 1996, HCFA administered a Medicare budget of \$196.6 billion. *Id.* at 82.

The Medicare program consists of two separate insurance programs. "Hospital Insurance," established by Part A of Title XVIII, provides certain benefits covering inpatient hospital, nursing facility, home health, and hospice services. "Supplementary Medical Insurance," established by Part B of Title XVIII, provides benefits in the areas of outpatient hospital visits, physician services, durable medical equipment, and diagnostic tests.

The Medicare Act itself is highly intricate and complex, currently consuming 430 pages in the United States Code. The statute and the regulations promulgated by the Secretary under that statute comprise a complicated and often seemingly contradictory maze for the reimbursement of covered health care services to Medicare beneficiaries. As one court of appeals commented, the statute and regulations of the Medicare program "are among the most completely impenetrable texts within human experience." *Rehabilitation Ass'n of Virginia, Inc. v. Kozlowski*, 42 F.3d 1444, 1450 (4th Cir. 1994).

In order to be eligible to receive payment for services rendered to Medicare beneficiaries, health care providers, such as hospitals, must enter into provider agreements and satisfy "Conditions for Participation" relating to beneficiary health, safety, and care. 42 U.S.C. § 1395x(e); 42 C.F.R. Part 482. The Secretary enters into agreements with "state survey agencies" ("SSA") to conduct inspections or "surveys" of participating hospitals to determine compliance with the Conditions of Participation and other

requirements.² See 42 U.S.C. § 1395aa. Although the SSA conducts the survey and makes a recommendation, the Secretary renders the final determination regarding certification. The Secretary has published instructions that an SSA must employ to conduct these surveys, including a detailed set of procedures known as the "State Operations Manual" ("SOM"). If the SSA finds noncompliance with a Condition of Participation – in other words, a deficiency – it reports that fact in writing to the facility in a "Statement of Deficiencies." The regulations require that a facility submit a written "Plan of Correction" that indicates the corrective action that the facility plans to take for each deficiency. 42 C.F.R. § 488.28. The SOM provides for the "monitoring" of a hospital to determine whether the hospital actually implements the corrective action and whether the corrective action is effective. See SOM § 3254.

When the deficiencies pose an "immediate and serious threat to patient health or safety," SSA monitoring begins immediately and termination procedures commence. See SOM § 3274; see also 42 C.F.R. § 489.53. A finding of an "immediate and serious threat to patient health or safety" is essential to this "fast-track" termination. No statute, however, defines this standard, although the SOM contains instructions to SSAs regarding the finding. SOM § 3010A. The Secretary's regulations provide for an opportunity to appeal HCFA's decision to an administrative law judge ("ALJ"). See 42 C.F.R. § 498.1, et seq. See generally 42 U.S.C. § 1395cc(h); 42 C.F.R.

² Under certain circumstances, accreditation by certain third-party organizations can substitute for this survey process. 42 U.S.C. §§ 1395x(e), 1395bb; 42 C.F.R. § 488.5. Many hospitals participate in the Medicare program through accreditation by the Joint Commission on Accreditation of Healthcare Organizations.

§ 489.53(d). However, any relief obtained by the provider through an appeal often comes too late – after the Secretary's actions have caused irreparable injury and sometimes after a facility has been closed. A hearing on the merits often is not available until after the termination has been completed.

Moreover, during this hearing process, the ALJ cannot entertain constitutional or statutory challenges to the Secretary's rules and regulations, or challenges to the propriety of the hearing and appeal process itself. See *Bowen v. Michigan Academy of Family Physicians*, 476 U.S. 667, 676 n.6 (1986) (Medicare manual specifically prohibits administrative law judge from commenting on constitutionality of Medicare Act or regulations); HHS CARRIER'S MANUAL § 12016 ("The HO [Hearing Officer] may not overrule the provisions of law or interpret them in a way different than HCFA does when he disagrees with their intent; nor may he use hearing decisions as a vehicle for commentary upon the legality, constitutional or otherwise, of any provision of the Act or regulations."); Petitioner's Brief at 44-45 ("constitutional contentions" and "challenges to the Secretary's regulations, ordinarily would not be the subject of an administrative hearing. Neither the Department Appeals Board nor individual ALJs are free to depart from statutory and regulatory requirements."). The administrative review process accordingly does not result in the creation of any "administrative record" for such claims.

In 1987, Congress amended the Social Security Act with the Omnibus Budget Reconciliation Act ("ORBA"), Pub. L. No. 100-203 (1987). The amendments, among other things, require stricter guidelines and penalties for nursing facilities not satisfying minimum health and safety standards. 42 U.S.C. § 1395i-3. In this case, Long

Term Care points out that after the Secretary implemented these new regulations, the percentage of nursing homes in Illinois found out of compliance with the requirements of Medicare and Medicaid jumped from 6% to nearly 70%. (Respondent's Brief in Opposition ("Res. Br.") at 2) Long Term Care alleges that this drastic change occurred because the new regulations are vague and leave too much discretion to the individual inspectors. (*Id.*) The Secretary has also proposed voluminous regulations concerning the conditions for the participation of hospitals. See 62 Fed. Reg. 66726 (Dec. 19, 1997). If implemented, hospitals and the trade associations that represent them, like the AHA, likewise may have constitutional or statutory challenges to those regulations.

Once they become eligible to participate in Medicare, providers submit claims for reimbursement for the provision of health care services. HCFA does not itself evaluate the millions of claims submitted by Medicare providers; federal contractors administer most of the program. "Fiscal Intermediaries," generally state Blue Cross programs, process and pay claims under Part A, and "Carriers," usually insurance companies, process and pay Part B claims. 42 U.S.C. §§ 1395u(a) to (b), 1395u(b)(3), 1395ff; 42 C.F.R. §§ 405.710, 405.821 to .850. A hospital or other provider dissatisfied by an adverse benefit determination by a fiscal intermediary or carrier concerning a Part A claim in excess of \$1000 or a Part B claim in excess of \$500, respectively, is entitled to a hearing before a hearing officer designated by the fiscal intermediary or carrier. 42 U.S.C. § 1395ff(a); 42 C.F.R. §§ 405.1809 to .1833 (intermediary hearing procedures), 42 C.F.R. §§ 405.801 to .874 (Part B appeals); *see also* 42 C.F.R. §§ 405.724, 405.856, 405.1875, 417.632 (regarding appeal rights to HHS's Departmental Appeals Board). Providers must submit

disputed Part A claims in excess of \$10,000 to the Provider Reimbursement Review Board ("PRRB"). 42 U.S.C. § 1395oo; 42 C.F.R. §§ 405.1835 to .1873. HCFA's Administrator, in his or her sole discretion, may review any decision rendered by the PRRB. 42 C.F.R. § 405.1875; *see infra* discussion regarding the average cost and length of a PRRB appeal. Once the Secretary has reached a "final decision" with respect to either an eligibility or amount determination, Section 405(g) authorizes a health care provider to seek review by initiating an action in federal district court. 42 U.S.C. § 405(g).

SUMMARY OF ARGUMENT

As this Court has recognized, the Medicare Act involves a "reticulated statutory scheme," which comprehensively details the rights and duties of the beneficiaries, providers, and other participants in the program. *Bowen v. Michigan Academy of Family Physicians*, 476 U.S. 667, 675 (1986). When the Act prescribes an exclusive administrative mechanism for reviewing the Secretary's decisions, as it admittedly does for disputes involving individual benefit determinations, it says so explicitly. See 42 U.S.C. §§ 1395h, 1395u(a) to (b), 1395ff, 1395oo. However, as this Court recognized in *Michigan Academy*, nothing in the language of the Medicare Act, its legislative history, or its "statutory scheme" bars a constitutional or statutory challenge to the Secretary's rules and regulations where the challenge is unrelated, or "collateral," to an individual benefit determination.

A. Section 405(h) of the Social Security Act, 42 U.S.C. § 405(h), incorporated into the Medicare Act by 42 U.S.C. §§ 1395cc, 1395ff, and 1395ii, sets forth the limitations that Congress placed on judicial review under the Medicare Act. By its plain terms, Section 405(h) does not place any limitation on challenges to a regulation not

connected with a hearing on an individual claim for benefits under the Medicare Act. The legislative history of the 1965 Medicare Act and its amendments reinforce this conclusion and makes clear that Congress created an administrative review process to handle only the "trivial" and "quite minor" matters of individual eligibility and benefit determinations, which might otherwise flood the Courts. Congress did not intend for the administrative review process to address constitutional and statutory challenges to regulations that might affect substantial portions, or even all, of the health care field.

B. The Court should adhere to its holding in *Bowen v. Michigan Academy of Family Physicians*, 476 U.S. 667 (1986). In that case, the Court held that the language and legislative history of the Medicare Act and its amendments showed that Congress intended only to foreclose review of individual "amount determinations" and did not intend to bar review of "substantial statutory and constitutional challenges to the Secretary's administration" of the Medicare program. 476 U.S. at 680. *Michigan Academy* did not create a judicial "exception" to the statute, which this Court can now repeal, but instead determined Congress's intent concerning the Medicare Act. The amendments that Congress made to the Medicare Act in 1986 did nothing to change the relevant statutory language or legislative history. Congress's inaction in the face of the Court's decision in *Michigan Academy* suggests that the Court correctly determined Congress's intent in that case.

C. Public policy strongly supports reaffirmation of the Court's holding in *Michigan Academy*. Requiring constitutional and statutory challenges to the Secretary's regulations to endure the long, complex, and costly administrative review process serves only to allow the government to engage in a "war of attrition" to avoid

resolution of those claims. The administrative review process will not permit the development of a relevant factual record or allow for the refinement of issues because administrative hearing bodies cannot hear constitutional or statutory claims, nor can they comment on the constitutionality or validity of the rules and regulations involved. Moreover, the administrative review process does not provide for any participation by trade associations, leaving institutions like AHA unable to adequately advance their members' interests. Finally, as this Court recognized in *Michigan Academy*, 476 U.S. at 680 n.11, allowing immediate judicial review of such constitutional and statutory claims will not open the floodgates to millions of Medicare claims, but rather would make for a more efficient system by allowing the federal courts to determine the validity of a standard, often in a single case.

ARGUMENT

I. UNDER THE MEDICARE ACT, A FEDERAL DISTRICT COURT HAS JURISDICTION TO HEAR CONSTITUTIONAL AND STATUTORY CLAIMS WHICH ARE COLLATERAL TO AN INDIVIDUAL CLAIM FOR BENEFITS UNDER THE ACT.

A. THE LANGUAGE OF SECTION 405(h) SHOWS THAT CONGRESS DID NOT INTEND TO BAR FEDERAL DISTRICT COURT JURISDICTION OVER COLLATERAL CLAIMS.

The Medicare Act provides that an individual "dissatisfied with any determination" concerning his eligibility for the program, "the amount of benefits," or "any other denial of a claim for benefits" is entitled to a hearing "to the same extent as provided in [42 U.S.C. § 405(b)] and to judicial review of the Secretary's final decision after such hearing as provided in [42 U.S.C.

§ 405(g)].” 42 U.S.C. §§ 1395ff(a) and (b). The Act also provides that if a provider wishes to dispute a determination concerning compliance or certification under the Medicare Act, the provider is entitled to the hearing and review procedures under 42 U.S.C. §§ 405(b) and 405(g). 42 U.S.C. § 1395cc(h). *See also* 42 U.S.C. § 1395ii.

Section 405(g) authorizes a party to seek judicial review “after any final decision of the [Secretary] made after a hearing to which he was a party.” 42 U.S.C. § 405(g). The next section, Section 405(h) states:

The findings and decision of the [Secretary] after a hearing shall be binding upon all individuals who were parties to such hearing. No findings of fact or decision of the [Secretary] shall be reviewed by any person, tribunal, or government agency except as herein provided. No action against the United States, the [Secretary], or any other officer or employee thereof shall be brought under section 1331 or 1346 of Title 28 to recover on any claim arising under this subchapter.

42 U.S.C. § 405(h). The Secretary contends that these provisions provide an “exclusive mechanism for obtaining judicial review of claims ‘arising under’ the Medicare Act,” (Brief for the Petitioners (“Pet. Br.”) at 18), including pre-enforcement challenges to her regulations under the Constitution and statutes of the United States. However, as this Court recognized in *Bowen v. Michigan Academy of Family Physicians*, 476 U.S. 667 (1986), nothing in the language of 405(h), its legislative history, or the statutory framework of Medicare bars such pre-enforcement challenges.

1. The Court should begin with the language of Section 405(h). As the Court has explained, the “lodestar is the language of the statute.” *United States v. Erika, Inc.*, 456 U.S. 201, 206 (1982). Nothing in the language of

Section 405(h) bars pre-enforcement judicial review of a challenge that is collateral to a claim for benefits under the Medicare Act, such as the claims brought by Long Term Care.

The first sentence of Section 405(h) makes the “findings and decision of the [Secretary] after a hearing” binding on the parties to the hearing. It does not otherwise limit judicial review. The second sentence limits judicial review of the “findings of fact and decisions of the Secretary” to the mechanisms established by the Medicare Act. This limitation, however, does not apply to pre-enforcement challenges that are collateral to a claim for benefits. The first sentence defines the terms “findings of fact” and “decision” as determinations made by the Secretary after a hearing. This Court has held that these terms have the same meaning in the second sentence. *Michigan Academy*, 476 U.S. at 679 n.8 (identifying “the contextual definition of ‘decision’ in the first sentence [of Section 405(h)] as those determinations made by ‘the Secretary after a hearing’”). *See generally, Mathews v. Eldridge*, 424 U.S. 319, 328 (1976) (the term “final decision” requires that “a claim for benefits shall have been presented to the Secretary”). A pre-enforcement challenge to a regulation on constitutional or statutory grounds, which is collateral to a claim for benefits, does not seek review of any “finding of fact” or “decision” of the Secretary made “after a hearing.” Rather, it seeks review of a rule or regulation before any hearing or decision. The plain language of the second sentence of 405(h) therefore does not bar judicial review of such a pre-enforcement challenge.

The Secretary recognizes that her “regulations and guidelines are not themselves ‘decisions’ of the Secretary within the meaning of the second sentence” of Section 405(h), but argues that applying Section 405(h) as written would allow “any plaintiff” to “bypass the Medicare

Act's exhaustion requirements at will by filing a declaratory judgment action." (Pet. Br. at 41 n.22) In making this argument, she relies on the Court's decision in *Heckler v. Ringer*, 466 U.S. 602 (1984). (*Id.*) *Ringer*, however, involved substantially different facts from those presented here. In that case, *Ringer* sought to overturn a regulation which denied benefits for an operation that he had not yet had. The Court accordingly viewed the lawsuit as seeking to recover on a claim of benefits, even though *Ringer* had not yet formally made such a claim: "Although it is true that *Ringer* is not seeking the immediate payment of benefits, he is clearly seeking to establish a right to future payments should he ultimately decide to proceed with [the] surgery." *Ringer*, 466 U.S. at 621. In contrast to *Ringer*, the constitutional and statutory claims brought by Long Term Care in this case are admittedly unrelated – in other words, collateral – to any particular claim for benefits. Immediate judicial review of claims unrelated or collateral to an individual claim for benefits will not allow participants in the Medicare Program to bypass the administrative review mechanisms. The second sentence of Section 405(h) therefore does not limit a federal district court's jurisdiction over those claims. *See Thunder Basin Coal Co. v. Reich*, 510 U.S. 200, 212 (1994) ("This Court previously has upheld district court jurisdiction over claims considered 'wholly "collateral"' to a statute's review provisions and outside of the agency's expertise") (citing cases).

2. The third sentence of Section 405(h) likewise does not bar a lawsuit seeking judicial review of the Secretary's regulations, but instead precludes only actions "to recover on any claim arising under this subchapter." The court of appeals correctly read the third sentence to cover only those cases seeking to recover on individual benefit

claims, and not a pre-enforcement challenge to a regulation as invalid that seeks only equitable relief: "[P]re-enforcement review of a regulation's validity is not an action to 'recover on' a claim, even when per [Weinberger v. Salfi, 422 U.S. 522 (1975)] a constitutional objection to the regulation is a 'claim arising under this subchapter.'" 143 F.3d at 1075-76. The language of Section 405(h) thus makes clear that Congress sought only to ensure that actions seeking to establish an individual's right to benefits go through the administrative review process.

3. The Secretary cannot suggest that the silence of Sections 405(g) and (h) concerning collateral challenges means that Congress intended to preclude judicial review of those challenges. As this Court has explained, it "customarily" refuses "to treat such silence 'as a denial of authority to [an] aggrieved person to seek appropriate relief in the federal courts.'" *Reno v. Catholic Social Servs., Inc.*, 509 U.S. 43, 56-57 (1993) (quoting *Stark v. Wickard*, 321 U.S. 288, 309 (1944)); *see also, Abbott Lab. v. Gardner*, 387 U.S. 136, 141 (1967) ("The mere fact that some acts are made reviewable should not suffice to support an implication of exclusion as to others. The right to review is too important to be excluded on such slender and indeterminate evidence of legislative intent.'") (quoting LOUIS L. JAFFE, JUDICIAL CONTROL OF ADMINISTRATIVE ACTION 357 (1965)). Put another way, if Congress had intended to bar pre-enforcement constitutional and statutory challenges, "it could easily have used broader language." *McNary v. Haitian Refugee Ctr., Inc.*, 498 U.S. 479, 494 (1991).

4. The language of Section 405(g) reinforces the conclusion that Section 405(h) applies only to individual claims for benefits. Section 405(g) provides, in part, that the "findings of the [Secretary] as to any fact, if supported by substantial evidence, shall be conclusive." The

use of a substantial evidence standard, which is inapplicable to constitutional or statutory challenges, suggests that Congress did not intend the Medicare Act's review provisions to apply to such pre-enforcement challenges to the Secretary's regulations where the challenge is collateral or unrelated to a particular claim for benefits. *See McNary*, 498 U.S. at 493 (abuse of discretion standard "lends substantial credence" to conclusion that the Immigration Reform and Control Act does not apply to challenges to the Immigration and Nationalization Services' practices and procedures); *Lindahl v. Office of Personnel Mgmt.*, 470 U.S. 768, 779 n.12 (1985) ("The juxtaposition of the finality language with the language concerning OPM's determinations of 'the facts' of disability arguably suggests that the finality language does not extend to procedural or legal questions."). The language of Sections 405(g) and (h) thus does not bar claims such as those brought by Long-Term-Care.

B. THE LEGISLATIVE HISTORY HIGHLIGHTS THAT CONGRESS INTENDED ONLY TO PRECLUDE JUDICIAL REVIEW OF INDIVIDUAL AMOUNT DETERMINATIONS AND NOT COLLATERAL CHALLENGES.

The legislative history of the Medicare Act, which this Court reviewed extensively in *Michigan Academy*, underscores that Congress intended to require only that plaintiffs seeking to recover on individual benefits claims proceed through the administrative review process, not that constitutional challenges to regulations endure the same process. By establishing the administrative review mechanisms of Section 405(g), Congress intended only to protect the federal courts from the flood of "trivial" and "quite minor" individual benefit claims that otherwise might result. *See Michigan Academy*, 476 U.S. at 680. It did

not intend to restrict access to the federal courts for challenges to the regulations that might substantially and immediately impact hundreds or thousands of providers and beneficiaries at the same time.

1. The Medicare Act was amended in 1972. The remarks of Senator Bennett, "as those of the sponsor of the language ultimately enacted, are an authoritative guide to the statute's construction." *North Haven Bd. of Educ. v. Bell*, 456 U.S. 512, 526-27 (1982). *See also Grove City College v. Bell*, 465 U.S. 555, 567 (1984) (same). Senator Bennett's introductory remarks make clear that Congress intended to restrict access to the courts only for "trivial" and "quite minor matters" concerning amount determinations:

The situations in which medicare decisions are appealable to the courts were intended in the original law to be greatly restricted in order to avoid overloading the courts with quite minor matters. The law refers to "entitlement" as being an issue subject to court review and the word was intended to mean eligibility to any benefits of medicare but not to decisions on a claim for payment for a given service.

If judicial review is made available where any claim is denied, as some court decisions have held, the resources of the Federal court system would be unduly taxed and little real value would be derived by the enrollees. The proposed amendment would merely clarify the original intent of the law and prevent the overloading of the courts with trivial matters because the intent is considered unclear.

118 Cong. Rec. 33992 (1972).

2. After closely examining Senator Bennett's remarks, as well as the remainder of the Medicare Act's 1965 and 1972 legislative history, the *Michigan Academy*

Court concluded that they accurately reflected the intent of Congress:

The legislative history of both the statute establishing the Medicare program and the 1972 amendments thereto provides specific evidence of Congress' intent to foreclose review only of "amount determinations" – i.e., those "quite minor matters," remitted finally and exclusively to adjudication by private insurance carriers in a "fair hearing." By the same token, matters which Congress did not delegate to private carriers, such as challenges to the validity of the Secretary's instructions and regulations, are cognizable in courts of law.

476 U.S. at 680 (quoting 118 Cong. Rec. 33992 (1972) (footnote omitted)). The challenge to the Secretary's regulations and guidelines brought by Long Term Care is thus "cognizable in courts of law."

3. The Secretary's discussion of this legislative history is incorrect. The Secretary thrice quotes the same fourteen words from the Senate Report accompanying the 1965 Medicare Act in support of her argument that Long Term Care's challenges must be brought within the mechanism outlined in Section 405(g): "It is intended that the remedies provided by these review procedures shall be exclusive." (Pet. Br. at 16, 22, 33) (quoting S. Rep. No. 89-404, at 55 (1965)) However, as this Court has previously recognized, the language relied upon by the Secretary does not address challenges to the methods by which the Secretary arrives at her decisions:

That Congress did not preclude review of the method by which Part B awards are computed (as opposed to the computation) is borne out by the very legislative history we found persuasive in *Erika*. The Senate Committee Report on the original 1965 legislation reveals an intention to preclude "judicial review of a determination

concerning the amount of benefits under part B where claims will probably be for substantially smaller amounts than under part A."

Michigan Academy, 476 U.S. at 676-77 (quoting S. Rep. No. 89-404, at 54-55 (1965)). Long Term Care's suit does not contest any benefit or eligibility determination by the Secretary and therefore the limitation of judicial review referenced by the Secretary's legislative history does not address the challenge brought by Long Term Care.

C. NOTHING IN THE STATUTORY SCHEME SUGGESTS AN INTENTION TO BAR CHALLENGES THAT ARE COLLATERAL TO AN INDIVIDUAL CLAIM FOR BENEFITS.

The Court may find an intention of Congress to preclude judicial review of an agency's rules and regulations when such an intent is "fairly discernable in the statutory scheme." *Thunder Basin*, 510 U.S. at 207 (quoting *Block v. Community Nutrition Inst.*, 467 U.S. 340, 351 (1984) (citation omitted)). The statutory scheme of the Medicare Act, however, does not suggest any intention to preclude pre-enforcement constitutional or statutory challenges that are collateral to an award of benefits.

1. As this Court has recognized in analyzing the scope of judicial review of the decisions of other federal agencies, "the factual 'question'" of an individual's entitlement to benefits "is quite distinct from questions of what laws and procedures the [agency] must apply in administering" the agency's responsibilities. *Lindahl*, 470 U.S. at 779. See also *McNary*, 498 U.S. at 493 (distinguishing between denials of individual applications and collateral challenges to INS procedures and practices); *Traynor v. Turnage*, 485 U.S. 535, 542-45 (1988) (statutory prohibition of judicial review of Veterans Administration benefit

determinations did not preclude jurisdiction over collateral statutory claim); *Michigan Academy*, 476 U.S. at 678-680 (distinguishing between challenges to the amount of Medicare payments and challenges to the method by which the Secretary determines such amounts); *Bowen v. City of New York*, 476 U.S. 467, 484 (1986) (challenge to procedure used by Social Security Administration "is materially distinguishable from one in which a claimant sues in district court, alleging mere deviation from the applicable regulations in his particular administrative proceeding"). Congress's decision to route individual claims concerning the amount of benefits through an administrative review process therefore does not suggest a similar intent concerning constitutional and statutory challenges to the Secretary's regulations.

2. The Secretary argues that when the Medicare Act provides a mechanism for obtaining review, that mechanism is exclusive. (Pet. Br. at 23-26) This argument misses the point. By its terms, Section 405(g) provides only for administrative review of individual amount determinations. It does not provide for review of constitutional and statutory challenges to the Secretary's regulations and guidelines. Nor, as a practical matter, are such claims reviewable. As the Secretary admits, Long Term Care's "constitutional contentions and its challenges to the Secretary's regulations, ordinarily would not be the subject of an administrative hearing. Neither the Department Appeals Board nor individual ALJs are free to depart from statutory and regulatory requirements." (Pet. Br. at 44-45) Congress instead designed the administrative review process to handle those "quite minor matters" related to the determination of benefits in individual cases. By the same token, matters for which Congress did not establish a review process, such as challenges to the

validity of the Secretary's regulations, are accordingly cognizable in courts of law.

3. To support her argument, the Secretary points repeatedly to this Court's characterization of the Medicare Act's statutory scheme as "reticulated." (Pet. Br. at 16, 19, 50). This "reticulated" scheme, however, does not suggest that the Court should route collateral challenges to regulations through the administrative review process. To the contrary, the reticulated nature of the Medicare Act is precisely what led this Court to earlier conclude that challenges mounted directly against the Secretary's regulations are not barred, because such challenges are nowhere addressed in the Act:

The reticulated statutory scheme, which carefully details the forum and limits of review of "any determination . . . of . . . the amount of benefits under Part A," and of the "amount . . . of payment" of benefits under Part B, simply does not speak to challenges mounted against the method by which such amounts are to be determined rather than the determinations themselves.

Michigan Academy, 476 U.S. at 675 (quoting 42 U.S.C. §§ 1395ff(b)(1)(C) and 1395u(b)(3)(C)). The Medicare Act's statutory scheme thus does not support foreclosing claims, such as Long Term Care's, that the plain language of Sections 1495(g) and (h) does not address.

II. NOTHING IN THE 1986 AMENDMENTS TO THE MEDICARE ACT ALTERED THE LANGUAGE OR LEGISLATIVE HISTORY OF SECTION 405(g) AND 405(h). THE COURT THEREFORE SHOULD ADHERE TO ITS DECISION IN *MICHIGAN ACADEMY*.

In *Michigan Academy*, individual doctors and an association of family physicians filed suit to challenge the

statutory and constitutional validity of 42 C.F.R. § 405.504(b). 476 U.S. at 668. The challenged regulation authorized the payment of benefits in different amounts for similar physicians' services. *Id.* The Secretary argued that Section 405(h) barred judicial review of all questions affecting the payment of benefits under the Medicare program. *Id.* at 669. After carefully reviewing the Medicare Act's legislative history, *Michigan Academy* held that "Congress intended to bar judicial review only of determinations of the amount of benefits to be awarded under Part B." *Id.* at 678.

A. Shortly after *Michigan Academy* was decided, Congress amended the Medicare Act to provide for judicial review of Part B benefit determinations to the same extent as Part A, thereby overruling the holding of *United States v. Erika, Inc.*, 456 U.S. 201 (1982). The Secretary argues that the 1986 amendment served to eliminate the "exception" to Section 405(h)'s limits on federal jurisdiction created by *Michigan Academy*. (See Pet. Br. at 36-37) The court of appeals, however, correctly identified the fatal flaw in the Secretary's argument – namely, that the 1986 amendments did not change the language of Section 405(g) and -(h). 143 F.3d at 1075-76. Nor did the legislative history of the 1986 amendment indicate any intention to alter the result reached in *Michigan Academy*.

The Court therefore has no reason to reconsider its analysis of Section 405(h) in *Michigan Academy*. To the contrary, Congress's failure to amend the controlling statutory language relied upon in *Michigan Academy* suggests Congress's implied assent to the continued application of that interpretation to the Medicare Act. "'Congress is presumed to be aware of an administrative or judicial interpretation of a statute and to adopt that interpretation when it reenacts a statute without change.'" *Lindahl*, 470 U.S. at 782 n.15 (quoting *Lorillard v. Pons*, 434 U.S. 575,

580 (1978)). See also *Cannon v. University of Chicago*, 441 U.S. 677, 696-697 (1979) ("It is always appropriate to assume that our elected representatives, like other citizens, know the law"); *Garrett v. United States*, 471 U.S. 773, 793-94 (1985) ("It is not a function of this Court to presume that 'Congress was unaware of what it accomplished.'") (citation omitted).

The court of appeals, moreover, correctly rejected the Secretary's characterization of *Michigan Academy* as establishing an "exception" to Section 405(h): "*Michigan Academy* does not say that a presumption of judicial review justifies an 'exception' to § 1395ii. It says, rather, that § 1395ii, read in light of its 1972 legislative history, affects only 'amount determinations.'" 143 F.3d at 1075 (citing *Michigan Academy*, 476 U.S. at 678-81). As this Court has acknowledged, it does not possess the authority to craft an "exception" to validly enacted legislation. "To allow otherwise 'would confer on the judiciary discretionary power to disregard the considered limitations of the law it is charged with enforcing.'" *Bank of Nova Scotia v. United States*, 487 U.S. 250, 254 (1988) (quoting *United States v. Payner*, 447 U.S. 727, 737 (1980)). As the Court lacked the power to craft an "exception" to the Medicare Act in 1986 when it decided *Michigan Academy*, it cannot judicially repeal any such "exception" now.

B. This Court also recognized the continuing validity of *Michigan Academy* after the 1986 amendment in *McNary v. Haitian Refugee Ctr., Inc.*, 498 U.S. 479 (1991). In *McNary*, the Court rejected the Commissioner of Immigration and Naturalization's reliance on *Heckler v. Ringer*, 466 U.S. 602 (1984), and expressly found that *Michigan Academy* applied to permit a collateral challenge to the Commissioner's regulations despite a jurisdictional limitation established by 8 U.S.C. § 1160(e)(1) for cases involving "a determination respecting an application for

adjustment of status." *McNary*, 498 U.S. at 494-99. See also *Thunder Basin*, 510 U.S. at 213 (citing *Michigan Academy* with approval)

C. In support of her argument, the Secretary relies upon a host of Supreme Court decisions: *Your Home Visiting Nurse Servs., Inc. v. Shalala*, 119 S. Ct. 930 (1999); *Heckler v. Ringer*, 466 U.S. 602 (1984); *United States v. Erika, Inc.*, 456 U.S. 201 (1982); *Califano v. Sanders*, 430 U.S. 99 (1977); *Mathews v. Eldridge*, 424 U.S. 319 (1976); and *Weinberger v. Salfi*, 422 U.S. 749 (1975). Each of these cases, however, concerns an attempt to recover on a claim for benefits under the Medicare Act as opposed to a collateral challenge to the Secretary's regulations. *Your Home* addressed the efforts of a Medicare provider to reopen its reimbursement determination. 119 S. Ct. at 933. *Ringer* involved a dispute over the payment of claims; in particular, challenges "to the payment of Medicare benefits for a surgical procedure known as bilateral carotid body resection." 466 U.S. at 604-05. *Erika*, which arose prior to the 1986 amendments, addressed whether federal court jurisdiction existed to "review determinations by private insurance carriers of the amount of benefits payable under Part B of the Medicare statute." 456 U.S. at 202. *Sanders* addressed a denied claim for disability benefits brought by an individual allegedly suffering from epilepsy and blackout spells. 430 U.S. at 102. *Eldridge* involved a challenge brought after the termination of Social Security disability benefit payments. 424 U.S. at 323. Last but not least, *Salfi* concerned the denial of insurance benefits under the Social Security Act. 422 U.S. at 753-54. None of those cases therefore is inconsistent with the Court's holding in *Michigan Academy*.

The Secretary makes much of this Court's holding in *Ringer* denying jurisdiction to one of the named plaintiffs, Freeman Ringer. (Pet. Br. at 24-25) Ringer brought suit to

challenge an agency rule that barred reimbursement for an operation he wished to undergo. Since Ringer had not yet had the surgery, his claim, the Secretary argues, is a "'pre-enforcement' action" the same as Long Term Care's action, and therefore *Ringer* bars Long Term Care's action. (*Id.* at 24) The Secretary, however, ignores this Court's observation that "[a]lthough it is true that Ringer is not seeking the immediate payment of benefits, he is clearly seeking to establish a right to future payments should he ultimately decide to proceed with [the] surgery." 466 U.S. at 621. Ringer's claim therefore was not collateral to an award of benefits, as are the claims brought by Long Term Care in this case, but instead was "inextricably intertwined with what we hold is in essence a claim for benefits and [therefore] § 1331 jurisdiction over all their claims is barred by § 405(h)." *Id.* at 624.

This case stands in stark contrast to *Ringer*. As the Secretary acknowledges, this case does not involve any "reference to any specific enforcement action." (Pet. Br. at 18) Long Term Care instead charges that the SOM used by inspection teams was adopted in violation of the Administrative Procedure Act and that the administrative appeals process under the Secretary's new regulations is so restrictive that it violates due process. Long Term Care also alleges that the Secretary's regulations are constitutionally vague, but the court of appeals dismissed this challenge after finding that it was not ripe for decision. The complaint in this case does not involve an effort to recover on a claim under the Medicare Act. It instead seeks relief from the uncertain punitive arm which hangs over its members, meting out punishment at a markedly increased rate since the challenged SOM and enforcement measures took effect, and for reasons and to a degree shrouded from view. Under the plain language of Section

405(h), as well as this Court's decision in *Michigan Academy*, those claims may proceed in federal court.

III. PUBLIC POLICY SUPPORTS THE ALLOWANCE OF CONSTITUTIONAL AND STATUTORY CHALLENGES TO REGULATIONS WHICH ARE COLLATERAL TO AN INDIVIDUAL CLAIM FOR BENEFITS.

The Medicare Act's rules and regulations provide for a lengthy, complicated, and costly administrative review process that does next to nothing to assist in the determination of constitutional and statutory challenges to the Secretary's rules and regulations. The only purpose served by forcing such constitutional and statutory challenges through this process is to allow the government to engage in a "war of attrition," with the hope that the "protracted delay" would discourage providers "from pursuing valid claims against the government." See Phyllis E. Bernard, *Empowering the Provider: A Better Way to Resolve Medicare Hospital Payment Disputes*, 49 ADMIN. L. REV. 269, 300 (1997). The Court should not require constitutional and statutory claims to proceed along such a tortuous route before being heard in a court of law.

A. Although Long Term Care's allegations here concern appeals through the Department Appeals Board of the HHS, the Court's decision in this case will likely impact not only that process, but also the other administrative review schemes established by the Secretary under the Medicare Act. One such appeals process that AHA and its members often must deal with is appeals through the PRRB. Although AHA has not located any data concerning the time and expense associated with appeals through the Department Appeals Board, the statistics concerning appeals through the PRRB underscore just

how onerous and long the process is, and how the Secretary's position is unfair and unjust.

In 1994, the PRRB commonly set hearing dates four years in advance, into 1998. See *Empowering the Provider*, 49 ADMIN. L. REV. at 281-82. Although procedures existed by which a provider could seek an expedited hearing, few took advantage of this route. *Id.* at 282. As one commentator has noted, this "long waiting period could easily be perceived as a means of rationing justice." *Id.* at 300. The legal and accounting costs of proceeding through the review process could "easily" amount to between \$25,000 and \$100,000. *Id.* at 279-80. The Administrator of HCFA may review a decision of the PRRB and may affirm, reverse, modify, or remand the case. 42 C.F.R. §§ 405.1871(b), 405.1875(g). Between 1975 and 1989, the Administrator reversed approximately one-half of the PRRB decisions that were favorable to providers. 49 ADMIN. L. REV. at 287 (citing David Holthaus, *First Step in Medicare Appeal Can Be A Long One*, HOSPITALS, May 5, 1989, at 40). "[T]he fact that HCFA reviews all board decisions and reverses many of them, diminishes the importance of the board and often makes arguing before it an exercise in futility." *Id.* at 286 (quoting *First Step*, at 40).

A provider who believes that the Secretary's rules and regulations violate constitutional or statutory limitations therefore lacks any realistic opportunity to seek judicial review through the PRRB under the Secretary's proposed construction of Sections 405(g) and 405(h). The provider must spend tens of thousands of dollars and many years proceeding through a process that admittedly cannot address the issues that the provider has raised. In the meantime, in order to have standing to bring its

claim, the provider must bear the burden of the Secretary's decision. The administrative review process therefore does not provide meaningful judicial review of constitutional and statutory challenges to the Secretary's rules and regulations. *See McNary*, 498 U.S. at 496-97 (the fact that undocumented aliens may challenge the INS's review procedures only if the surrender themselves for deportation "is tantamount to a complete denial of judicial review for most undocumented aliens").

B. Moreover, adopting the Secretary's construction of Sections 405(g) and 405(h) would unfairly limit a trade association's ability to bring constitutional and statutory claims on behalf of its members. This Court has held that trade associations have standing to bring claims on behalf of their members. *See Hunt v. Washington State Apple Advertising Comm'n*, 432 U.S. 333, 342-43 (1977) (even in the absence of a direct injury to itself, an association may have standing solely as a representative of its constituents). However, this standing depends "in substantial measure on the nature of the relief sought." *Id.* at 343 (quoting *Warth v. Seldin*, 422 U.S. 490, 515 (1975)). An association has standing to bring a claim only if "neither the claim asserted nor the relief requested requires the participation of individual members in the lawsuit." *Hunt*, 432 U.S. at 343. Permitting trade associations, such as AHA, to bring such claims allows the cost of challenging an allegedly improper regulation to be more fairly shared by all of the members of the field affected by that regulation, rather than placing the entire burden of challenging the regulation on an individual institution.

Accepting the Secretary's position would effectively eliminate the ability of trade associations to bring such claims. The rules and regulations promulgated by the Secretary limit the parties to "the affected party and HCFA or OIG, as appropriate" and make no provision for

any involvement by a trade association. 42 C.F.R. § 498.42. Moreover, a trade association may not have standing even after the provider has endured the administrative review process because a court may consider an action to review the Secretary's determinations concerning a particular provider to be limited to "the participation of individual members in the lawsuit." *Hunt*, 432 U.S. at 343.

C. The preclusion of meaningful judicial review is particularly problematic where it would serve no meaningful purpose to force providers to go through the tortuous administrative review process in order to assert constitutional and statutory claims. The Secretary argues that routing all challenges "through the administrative review process as a pre-condition to judicial review" would permit "development of a factual record," allow "for refinement of legal issues, enabling the agency to apply its expertise to the specific issues raised" and afford "the Secretary the opportunity to resolve the dispute on other grounds." (Pet. Br. at 18) However, given the limitations upon the power of the administrative tribunals, requiring a provider to first endure the administrative review process will not serve any of these purposes.

The administrative review process will not result in the compilation of a detailed record to assist the courts in reviewing the constitutional and statutory claims. As explained *supra*, administrative law judges lack jurisdiction to address claims regarding the SOM and the Secretary's enforcement measures. *See* 42 C.F.R. § 405.860. *See also Michigan Academy*, 476 U.S. at 676 n.6 (Medicare Manual expressly prohibits the hearing officer from overruling or commenting on the legality or unconstitutionality of any Medicare Act provision or regulation). Because the administrative law judges cannot address

such claims, they cannot develop a factual record for such claims. Moreover, it is not clear what, if any, assistance further factual development will provide. See *Thomas v. Union Carbide Agric. Prods. Co.*, 473 U.S. 568, 581 (1985) ("The issue presented in this case is purely legal, and will not be clarified by further factual development.").

Nor will the administrative review process allow "for refinement of legal issues" by "enabling the agency to apply its expertise to the specific issues raised." (Pet. Br. at 18) Since neither the ALJ nor the various appeals boards can even "comment upon" constitutional or statutory challenges to the Secretary's rules or regulations, *Michigan Academy*, 476 U.S. at 676 n.6, the administrative review process does not provide any opportunity for the agency to provide its expertise on those issues. Moreover, even if the ALJ or appeals board could comment on such challenges, they would not bring any particular expertise in evaluating those constitutional and statutory claims, as those claims involve the expertise particularly within the providence of the courts. See *Sanders*, 430 U.S. at 109 ("Constitutional questions obviously are unsuited to resolution in administrative hearing procedures and, therefore, access to the courts is essential to the decision of such questions."). The courts will have to address the same undigested legal issues regardless of whether the Medicare provider has exhausted its administrative remedies. Permitting the federal courts to address constitutional and statutory arguments in the first instance will thus not create a "risk [of] premature judicial interference" nor run the risk of "devastating consequences," (Pet. Br. at 27), for the Medicare Program.

The Secretary's third argument, that requiring administrative review will allow the Secretary to resolve the matter "on other grounds," (Pet. Br. at 18), does not advance a legitimate public interest. It is not in the public

interest to avoid resolving whether the Secretary's rules and regulations violate constitutional or statutory provisions; to the contrary, it furthers the public interest to ensure that such claims are resolved promptly, in order to fairly and effectively implement the intent of Congress. However, as explained *supra*, the delay and expense exacted by the administrative review process frustrates this worthy objective.

Finally, contrary to the Secretary's suggestions, permitting federal courts to hear pre-enforcement constitutional and statutory challenges will not exhaust the resources of the court system. In fact, as this Court has recognized, a timely challenge to an unconstitutional or unlawful enforcement measure may result in substantial economies by forestalling the filing of a myriad of individual claims raising the same arguments. See *Michigan Academy*, 476 U.S. at 680 n.11 ("'[P]ermitting review only [of] . . . a particular statutory or administrative standard . . . would not result in a costly flood of litigation, because the validity of a standard can be readily established, at times even in a single case.'") (quoting Note, *Congressional Preclusion of Judicial Review of Federal Benefit Determinations: Reasserting Separation of Powers*, 97 HARV. L. REV. 778, 792 (1984) (footnote omitted)).

Moreover, the federal courts have a well-established body of law to determine whether they can properly address and resolve a legal issue. As this Court has explained, *Abbott Labs*, 387 U.S. 136, 148-49 (1967), the ripeness doctrine serves "to prevent the courts, through avoidance of premature adjudication, from entangling themselves in abstract disagreements over administrative policies" as well as "to protect the agencies from judicial interference until an administrative decision has been formalized and its effects felt in a concrete way by the challenging parties." The court of appeals in this case

applied those principles in deciding which of Long Term Care's claims were ripe for adjudication, although Long Term Care disputes its ruling on some points. The decision of the court of appeals thus demonstrates that the Secretary's concern regarding the "serious risk that premature judicial interference could have devastating consequences for the [Medicare] program," (Pet. Br. at 27), is groundless.

CONCLUSION

For the reasons discussed above, the judgment of the court of appeals should be affirmed.

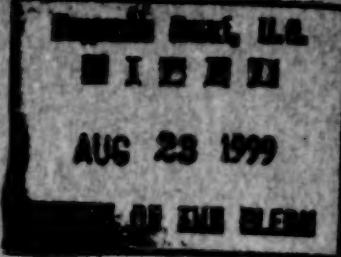
Dated: August 23, 1999.

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No. 98-1109

IN THE
SUPREME COURT OF THE UNITED STATES

DONNA E. SHALALA, SECRETARY OF HEALTH AND HUMAN SERVICES, ET AL, *Petitioners.*

v.

ILLINOIS COUNCIL ON LONG TERM CARE, INC., *Respondent.*

**ON WRIT OF CERTIORARI TO THE
UNITED STATES COURT OF APPEALS
FOR THE SEVENTH CIRCUIT**

**BRIEF OF AMICI CURIAE
AMERICAN HEALTH CARE ASSOCIATION,
NATIONAL SUBACUTE CARE ASSOCIATION, AND
NATIONAL ASSOCIATION FOR THE SUPPORT OF
LONG TERM CARE,
IN SUPPORT OF RESPONDENT**

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QUESTION PRESENTED

Whether 42 U.S.C. § 405(h), incorporated into the Medicare Act by 42 U.S.C. § 1395ii, eliminates jurisdiction under 28 U.S.C. §§ 1331 and 1346 over an action asserting constitutional and statutory challenges to Medicare regulations where the contentions alleged cannot be considered in the administrative review process and are unrelated to an individual claim.

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THE INTEREST OF *AMICI CURIAE*¹

The American Health Care Association, the National Subacute Care Association, and the National Association for the Support of Long Term Care. (collectively, "*Amici*") are national trade associations representing the interests of nursing homes, state nursing home trade associations, and entities providing items or services to nursing homes. The nursing homes represented by *Amici* are certified to participate in the Medicare or Medicaid programs, or both. An integral part of the mission of each association is to influence the government to invest in the well-being of the elderly and disabled, to assure access to long-term care services, and to achieve sound legislative and regulatory policies that support the efforts of the provider community to deliver professional and compassionate care to nursing facility residents.

Respondent Illinois Council on Long Term Care, Inc. ("Illinois Council") challenges the regulations and manual that the Secretary of the Department of Health and Human Services ("Secretary"), through the Health Care Financing Administration ("HCFA"), uses to survey skilled nursing facilities ("SNFs") for compliance with Medicare certification requirements and to impose remedies in the event of a facility's alleged failure to comply with such certification requirements. Contrary to the intent of Congress in enacting the Omnibus Budget Reconciliation Act of 1987, Pub. L. No. 100-203, 101 Stat. 1330 ("OBRA 1987"), *Amici*'s members' experience demonstrates that the Medicare survey, certification, and enforcement system is

¹ The parties have consented to the submission of this brief. Their letters of consent have been filed with the clerk of court. No counsel for a party authored this brief in whole or in part, and no person or entity, other than *amici curiae*, its members, or its counsel, made a monetary contribution to the preparation or submission of this brief.

fataally flawed, often leading to citations for minor imperfections or administrative infractions that do not affect resident care, and punitive rather than remedial sanctions. Moreover, when erroneous deficiencies are cited, facilities are precluded or significantly discouraged from appealing those citations and correcting their compliance records -- despite public disclosure of every facility's deficiency record at the facility, on the internet, and by state survey agencies.

Amici and the long-term care facilities, trade associations, and providers of items and services to long-term care facilities that they represent have a profound interest in ensuring for both themselves and facility residents that the Medicare survey, certification, and enforcement procedures are applied consistently among providers and that wrongful agency survey and enforcement actions can be heard and remedied without diverting resources from caregiving or unduly disrupting resident care. The inconsistent, arbitrary, and capricious application of survey standards and enforcement remedies undermines daily facility operations, resident care, and the ability of every Medicare beneficiary to choose a quality long-term care provider. Moreover, because the current survey and enforcement system does not permit a facility to challenge many abusive survey and enforcement determinations and procedures, a facility is powerless, in its individual capacity, to bring justice to a fundamentally flawed administrative system.

This case presents an important opportunity to challenge an administrative system that would otherwise never be subject to judicial scrutiny. *Amici* have a strong interest in the outcome of this case, and they support Respondent's efforts to challenge the systemic administrative inequities in the Secretary's nursing home survey and enforcement scheme.

SUMMARY OF ARGUMENT

Power tends to corrupt and absolute power corrupts absolutely.²

This case is about power: the power of an administrative agency to act without regard to its statutory authority or the Constitution; the power of an agency to act subject only to a review system of its own creation that deliberately insulates the agency's acts from judicial review. In essence, this case is about the "absolute power" that corrupts so absolutely.

Given the extraordinary power of the Secretary in this context, we argue that, in the limited circumstances presented in this case, a federal district court has the power, pursuant to 28 U.S.C. §§ 1331 and 1346, to hear Respondent's constitutional and statutory challenge to HCFA's nursing facility survey and enforcement regulations. This Court should not permit the otherwise watchful eye of the judiciary to ignore the abuses, excesses, and injustices that inevitably occur when an agency possesses absolute discretion unfettered by judicial review.

I. Respondent's constitutional and statutory challenges to the Secretary's Medicare survey and enforcement system for SNFs is not barred by 42 U.S.C. § 405(h), as incorporated into the Medicare Act by 42 U.S.C. § 1395ii, which provides that federal courts do not have jurisdiction under 28 U.S.C. §§ 1331 and 1346 with respect to actions brought to "recover on any claim arising under" the Medicare Act. The issues presented in this case are simply not a "claim" within the meaning of section 405(h).

² Bartlett, John, *Familiar Quotations* 615 (Emily M. Beck, ed., 15th ed. 1980).

Section 405(h) applies only to claims brought by individual providers or beneficiaries to recover Medicare benefits or reimbursement, or to challenge the termination or denial of a provider agreement. Because this is not a claim within the meaning of section 405(h), there is no administrative remedy to exhaust, and the United States Court of Appeals for the Seventh Circuit correctly held that the district court had subject matter jurisdiction over this important challenge.

II. Pre-enforcement judicial review of Respondent's challenge is warranted under this Court's decision in *Bowen v. Michigan Academy of Family Physicians* because the Secretary has promulgated a review scheme that is calculated to prohibit or strongly discourage judicial review of Respondent's challenge.

A. The Secretary's regulations preclude providers from appealing a number of significant determinations that go to the heart of whether a facility is deemed to provide quality care. For example, a facility may not appeal a deficiency citation for which no enforcement penalty or remedy is imposed -- despite the significant future ramifications of such citations, including widespread public disclosure of such deficiencies at the facility, by state survey agencies, and on the internet, and the use of such deficiencies to justify harsher enforcement remedies or "PPF" designation after a subsequent survey. The Secretary's review scheme also prohibits providers from appealing the Secretary's choice of remedy, regardless of the harshness of the remedy relative to the underlying deficiency or the inconsistency with which various remedies are imposed among providers on a local or regional basis. Further, providers generally are unable to appeal a determination regarding the "level of noncompliance," which is determined in part based on vague terms that purport to define the degree of harm that was or could be caused by the deficiency.

B. The Secretary's administrative review system prohibits providers from challenging the validity of the regulations with which they must comply. Constitutional or statutory challenges may not be raised in the informal dispute resolution procedure authorized for contesting survey findings. Moreover, the Secretary's administrative review procedures preclude administrative law judges ("ALJs") from addressing such challenges. Consequently, on the small chance that a provider has appealed a determination for which the Secretary's regulations permit an appeal, and the provider has finally reached federal court after exhausting its administrative remedies, there is no record for a court to review with respect to the constitutional or statutory challenge. In cases where a provider has challenged the imposition of a civil monetary penalty and must appeal directly to the federal circuit court of appeals, the appellate court is hindered by both the lack of an appropriate record and the inability to perform the fact-finding to create such a record.

C. Even when administrative or judicial review is available, such review is strongly discouraged by the Secretary and, as a practical matter, remains unavailable. The Secretary successfully prevents providers from pursuing their claims by advocating strict pleading requirements, which have no basis in the regulations. In addition, the time-consuming nature of the administrative review process further discourages providers from raising important constitutional and statutory challenges, especially since the Secretary's review scheme does not provide for expedited review of such collateral issues, which the HCFA Departmental Appeals Board ("DAB") and ALJs have no authority to decide. It is unjust and nonsensical to require providers to appeal constitutional and statutory issues on a piecemeal basis while the entire industry suffers during the intervening years from the illegal and unconstitutional practices and policies of the Secretary and when the end

result could be accomplished swiftly and efficiently in a single challenge by Respondent.

III. Pre-enforcement judicial review of Respondent's case should be permitted because such review does not violate the purposes of the doctrine of exhaustion of administrative remedies. In this case, pre-enforcement judicial review does not constitute premature interference with agency process because the administrative review body has no authority to address statutory or constitutional challenges. Moreover, such challenges are not within the realm of agency expertise, and the parties cannot compile a record to assist later judicial review. Judicial economy, on the other hand, dictates that Respondent's case be addressed immediately in a single ruling, thereby precluding the Secretary from violating the Constitution and exceeding her statutory authority to the detriment of this nation's long-term care providers and the residents to whom they provide care.

ARGUMENT

I. The Medicare Act Does Not Bar Pre-Enforcement Judicial Review Of A Statutory Or Constitutional Challenge

The Social Security Act jurisdictional bar, which is codified at 42 U.S.C. § 405(h) and made applicable to the Medicare program by 42 U.S.C. § 1395ii, provides that federal courts do not have subject matter jurisdiction with respect to any action "to recover on any claim arising under" the Medicare Act (emphasis added). Section 405(h) further provides that no finding of fact or decision of the Secretary may be reviewed by any tribunal except as provided in the Medicare Act. Section 405(g) permits aggrieved parties to obtain judicial review in federal district court of any "final decision" of the Secretary made after a hearing, thus requiring claimants to exhaust administrative remedies. 42 U.S.C. § 405(g).

For two simple and straightforward reasons, section 405 does not require exhaustion of administrative remedies for a statutory or constitutional challenge such as that raised here by Illinois Council. First, section 405(h) applies only to individual or provider actions to recover on a claim for Medicare *benefits or reimbursement*. Second, section 405(h) does not preclude pre-enforcement judicial review of constitutional and statutory claims -- even if those claims directly or indirectly involve Medicare benefits or reimbursement -- where delayed judicial review is not available.

A. Section 405(h) Applies Only To Claims For Benefits Or Reimbursement

Section 405(h) provides for judicial review of "findings of fact" and decisions of the Secretary made after a hearing. A critical reading of the context of section 405 confirms that such a hearing clearly was intended to adjudicate only claims for payment of benefits. In section 405(a), the Commissioner of Social Security is authorized to adopt procedures for establishing "the right to *benefits*" under Title II of the Social Security Act. In section 405(b)(1), the Commissioner is directed to make findings of fact and decisions regarding "the rights of any individual applying for a *payment*" under Title II. Section 405(b)(3)(A) sets forth the consequences for failure to timely request review of an adverse determination with respect to an individual's "application for any *benefit*" under Title II. Section 405(g) provides that an individual may obtain judicial review of the Secretary's final decision made after a hearing "irrespective of the *amount in controversy*." Finally, section 405(i) sets forth the procedure for authorizing payment of benefits after the Commissioner or a district court has found an individual eligible for such benefits.

The language of section 405 also evidences an intent that the hearing, exhaustion, and judicial review procedures

only apply to claims brought by individual beneficiaries or providers. Indeed, the seminal cases in which this Court has interpreted sections 405(h) and 405(g) have involved individual claims for benefits or reimbursement. *E.g.*, *Weinberger v. Salfi*, 422 U.S. 749 (1975) (Social Security survivor benefits); *Mathews v. Eldridge*, 424 U.S. 319 (1976); *Heckler v. Ringer*, 466 U.S. 602 (1984) (Medicare reimbursement for a surgical procedure). The availability of review under section 405 of provider agreement terminations³ provides further evidence that section 405 is limited to review of individual provider determinations and not major constitutional and statutory challenges to agency practices and procedures.

It is no surprise, then, that this Court has strictly enforced the exhaustion requirements for reimbursement or benefit claims brought by individuals. In *Heckler v. Ringer*, 466 U.S. at 614, this Court interpreted section 405(h) to preclude immediate judicial review of individual or provider claims that are “inextricably intertwined” with a benefit or reimbursement claim for which administrative remedies have not been exhausted. Where, at bottom, the claim at issue is one for reimbursement, this Court has required exhaustion of administrative remedies. *Id.*

This case, however, is very different from its predecessors. Illinois Council is not a provider certified to participate in the Medicare program. It has not sought to disguise a termination decision or claim for reimbursement as a constitutional issue in an effort to circumvent the

³ 42 U.S.C. § 1395cc(h)(1) provides that an institution dissatisfied with a determination by the Secretary that it is not a provider of services or with the Secretary’s determination to terminate its provider agreement shall be entitled to a hearing to the same extent as is provided in Section 405(b) and to judicial review of the Secretary’s final decision after a hearing.

jurisdictional bar. *Cf. Ringer*, 466 U.S. at 614 (disagreeing with the notion that claims construed as “procedural” in nature are cognizable in federal district court by way of federal question jurisdiction). Respondent’s request for relief would not, if granted, require merely “ministerial details” to be performed before receiving payment of reimbursement or reinstatement of its Medicare certification. *See id.* at 615. In sum, Respondent does not raise a routine or “quite minor matter” for judicial consideration. *See Bowen v. Michigan Academy of Family Physicians*, 476 U.S. 667, 677 (1986) (noting Congressional intent “to avoid overloading the courts with ‘quite minor matters’”).

Further, this case was not even brought by an individual provider, but by an association representing the interests of nursing facilities in Illinois. It asserts important constitutional and statutory issues that section 405, with its emphasis on individual claims, is not designed to address. Respondent challenges the legality of systemic agency practices and procedures which are dealt with most efficiently in a single case, thereby preventing a flood of similar litigation throughout the country. *See Michigan Academy* 476 U.S. at 680 n.11 (noting that regulatory challenge would not open the floodgates to millions of claims because the broad challenge at issue was not a “quite minor matter” properly confined to administrative review). As noted subsequently herein, Respondent’s case cannot be meaningfully addressed in the administrative process, nor can the violation of its members’ constitutional rights be adequately remedied retroactively upon judicial review.

In a nutshell, this case simply does not present a claim within the meaning of section 405(h). The challenged regulations do not constitute a “decision of the Secretary,” which section 405(h) excepts from review by any tribunal. As this Court noted in *Michigan Academy*, a contrary conclusion “would ignore the contextual definition of ‘decision’ in the first sentence [of section 405(h)] as those

determinations made by the Secretary after a hearing.” 476 U.S. at 679 n.8. This Court recognized that where, as here, judicial review is not available as a legal or practical matter, a regulatory challenge is not subject to section 405(h) because *there is no administrative remedy to exhaust.* *Id.*

B. Section 405(h) Does Not Preclude Pre-Enforcement Judicial Review Of Collateral Constitutional And Statutory Challenges

Nothing in section 405 or the remainder of the Social Security Act explicitly precludes pre-enforcement review of actions brought to challenge the unconstitutional or otherwise unlawful practices and policies of an administrative agency. As this Court has recognized on more than one occasion, there exists a “strong presumption that Congress intends judicial review of agency action.” E.g., *Michigan Academy*, 476 U.S. at 670; *McNary v. Haitian Refugee Ctr. Inc.*, 498 U.S. 479, 496 (1991). Accordingly, not all statutory or regulatory challenges involving the Medicare Act are barred by section 405(h) or are required to proceed through administrative review.

Although judicial review historically has been denied where a provider or beneficiary has failed to exhaust administrative remedies, this Court has permitted immediate judicial review for constitutional claims that were collateral to a claim for payment. *Eldridge*, 424 U.S. 319 (1976). In *Mathews v. Eldridge*, this Court held that the district court had jurisdiction to decide a constitutional issue that was collateral to a claim for disability benefits, despite the fact that the respondent had not exhausted his administrative remedies. *Id.* at 331. This Court found that the respondent raised a colorable constitutional claim that justified immediate review because a denial of disability benefits “would damage him in a way not recompensable through retroactive payments.” *Id.* Accordingly, this Court waived

the respondent’s obligation to exhaust his administrative remedies. *Id.* at 331-32. The exhaustion requirement may similarly be waived if it would be futile to pursue administrative remedies. *Salfi*, 422 U.S. at 767 (noting that exhaustion may be futile where the only issue to be resolved is a matter of constitutional law beyond the Secretary’s competence to resolve).

Immediate judicial review also has been permitted where review of “substantial statutory and constitutional challenges” to the Secretary’s administration of the Medicare program would be otherwise foreclosed. *Michigan Academy*, 476 U.S. at 680; see also *McNary*, 498 U.S. 479 (permitting constitutional challenge to agency practices and procedures where meaningful judicial review was unavailable as a practical matter). In *Michigan Academy*, an association of family physicians and several individual physicians challenged the validity of a regulation governing the methodology for determining physician reimbursement under Medicare Part B. At the time *Michigan Academy* was decided, the Medicare statute explicitly authorized judicial review of determinations regarding the amount of payments under Part A but not under Part B. This Court rejected the government’s assertion that Congress contemplated administrative review of “trivial” monetary claims, but intended no review of statutory and constitutional challenges. 476 U.S. at 680. Recognizing instead the “strong presumption” that Congress intends judicial review of agency action, this Court held that the respondents’ claims were not barred by section 405(h). *Id.* at 670.

Similarly, in *McNary*, this Court held that two organizations and several individuals could bring a due process challenge to Immigration and Naturalization Service (“INS”) amnesty determination procedures where respondents “would not, as a practical matter, be able to obtain, meaningful judicial review.” 498 U.S. at 496. The statute at issue expressly provided that judicial review of

adverse amnesty determinations could only occur in the context of deportation or exclusion proceedings. This Court also held that the relevant jurisdictional bar did not preclude the respondents' claims because they did not seek review on the merits of an amnesty determination. *Id.* at 494.

For a variety of reasons, meaningful judicial review of the claims in *McNary* was not possible. Applicants for amnesty were precluded from developing an adequate record for judicial review. *Id.* at 496. In addition, because review of an adverse amnesty determination could only be reviewed in the context of a deportation proceeding, an undocumented alien seeking review of such a determination would have to voluntarily surrender for deportation, thus virtually assuring that no review would be had. Finally, this Court recognized that the forum for judicial review -- the federal circuit courts of appeal -- would lack the fact-finding and record-developing capabilities of a district court.

As discussed below, the case at bar fits squarely into the exception this Court has delineated for those collateral issues for which meaningful judicial review is otherwise foreclosed.

II. Immediate Judicial Review Of Respondent's Challenge Is Warranted Under *Michigan Academy* Because Such A Challenge Is Otherwise Incapable Of Receiving Meaningful Review

Respondent's legal challenges are incapable of receiving meaningful administrative or judicial review because the Secretary has promulgated an unprecedented review scheme that either completely prohibits review or strongly discourages providers from seeking review of certain determinations. Contrary to the Secretary's assertion

that judicial review is merely delayed,⁴ the fact is that, for a variety of reasons, review is nearly impossible to obtain. Consequently, the inconsistencies in the survey and enforcement process, which OBRA 1987 was designed in part to address,⁵ continue to persist. Efforts to challenge or address these inconsistencies divert valuable facility staff and resources from caregiving, and frustrate facility attempts to comply with applicable standards and to provide quality resident care. Ultimately, these inconsistencies prevent beneficiaries from receiving a fair and accurate assessment of the quality of care at a particular facility.

Congress could not have intended such a result, and it is disingenuous for the Secretary to suggest otherwise when it is she, and not Congress, who has precluded review of critical agency determinations. Although we do not dispute that section 405(g) sets forth the exclusive review mechanism for the vast majority of provider disputes, this case presents a exception to that review process. A decision to the contrary would be tantamount to writing a "blank check[] drawn to the credit of some administrative officer or board." *Michigan Academy*, 476 U.S. at 671 (quoting S. Rep. No. 752, 79th Cong., 1st Sess. 26 (1945)). Failure to allow pre-enforcement judicial review of the Secretary's regulations and manual provisions would similarly be giving the Secretary *carte blanche* to issue deficiencies and to impose remedies without giving providers, in many cases, the ability to challenge the agency action.

⁴ Petitioner's Brief ("Pet. Brf.") at 38.

⁵ Omnibus Budget Reconciliation Act of 1987, Pub. L. No. 100-203, § 4202, 101 Stat. 1330-174 (codified at 42 U.S.C. § 1395i-3(g)(2)(D) (requiring implementation of programs to reduce inconsistencies in survey results)).

A. *Medicare Regulations Prohibit Review
Of Respondent's Constitutional
Challenge*

The administrative review mechanisms set forth in section 405(g) are incapable of addressing statutory, regulatory, or constitutional challenges. When a provider undergoes a survey and is cited for deficiencies, it may dispute these deficiencies directly with the surveyors pursuant to the informal dispute resolution procedure authorized by 42 C.F.R. § 488.331(a). However, providers may use that procedure only to refute survey findings; the validity of the regulations that form the basis for a survey deficiency cannot be challenged. *See id.* Moreover, the failure of HCFA or the state agency to complete informal dispute resolution in a timely manner will not delay any enforcement action, and the facility is expressly precluded from seeking any such delay. *Id.* § 488.331(b).

In addition, in hearing a facility's appeal of the imposition of civil money penalties ("CMPs"), ALJs have no authority to determine the validity of the underlying federal statutes or regulations or to enjoin any act of the Secretary. - 42 C.F.R. § 1005.4(c)(1), (4); *Care Inn of Gladewater*, No. A-98-61, DAB 1680 (March 2, 1999), reprinted in Medicare and Medicaid Guide (CCH) ¶ 120,041; *Birchwood Manor Nursing Ctr.*, No. A-98-66, DAB 1669 (Sept. 4, 1998). Moreover, there is no "expedited review" procedure to permit immediate judicial review of survey, certification, and enforcement determinations that involve solely the validity of a statute or regulation. Cf. 42 U.S.C. § 1395oo(f)(1) (authorizing judicial review of reimbursement determinations made by fiscal intermediaries if such determinations involve questions of law or regulation and the ALJ determines on its own motion or on the provider's motion that it is without authority to decide such questions).

Because ALJs do not have the authority to address constitutional or statutory challenges, providers have no opportunity to develop a record on such issues for later judicial review. This is especially critical in those cases involving the imposition of CMPs because judicial review of this type of penalty is available only in a federal court of appeals. As a general matter, fact-finding and record developing capabilities are not within the expertise of the court of appeals. In contrast, these tasks are germane to the federal district courts. For this and other reasons, this Court found in *McNary* that restricting judicial review to the courts of appeals for a particular amnesty determination of the INS was the "practical equivalent of a total denial of judicial review of generic constitutional and statutory claims." 498 U.S. at 497.

The Secretary's reliance on *Thunder Basin Coal Co. v. Reich*, 510 U.S. 200 (1994), is misplaced. See Pet. Brf. at 20, 32, and 49. In *Thunder Basin*, this Court held that a pre-enforcement regulatory challenge was precluded by the administrative review scheme of a federal mining act that provided for review of statutory and constitutional issues by an independent commission. *Id.* at 216. This Court found that such claims could receive meaningful administrative review because the reviewing body was an independent entity and not the agency itself, which is clearly not the case here. *Id.* at 215. This Court also was persuaded by the availability of subsequent review in the federal court of appeals. However, because the independent commission had the authority to review constitutional or regulatory challenges, it was capable of building an adequate record for appellate court review.

As in *McNary*, Illinois Council seeks review of unlawful practices and policies adopted by a federal agency in administering a federal program. As in *McNary*, the inability of courts of appeals to review or develop a record that adequately reflects the manner in which HCFA

administers the survey and enforcement process is a severe impediment to adequate and meaningful judicial review.

B. The Challenged Regulations Prohibit All Review Of Significant Survey And Enforcement Actions

When a nursing facility is surveyed by a state agency⁶ and cited for one or more deficiencies, the state agency may recommend that the Secretary impose one or more remedies. The recommended remedies depend on the scope and severity of the deficiency citations, but may include, among other things, state monitoring, denial of payment, CMPs, temporary management, and termination of the provider agreement. 42 U.S.C. § 1395i-3(h); 42 C.F.R. §§ 488.406, 488.408. The challenged regulations prohibit review of a number of very significant survey and enforcement determinations, including the following: issuance of deficiencies without the imposition of a remedy; the government's choice of remedy; and determinations regarding the level of noncompliance. These determinations have a fundamental impact on facility operations and the Secretary's assessment of the quality of care provided at a facility. Thus, these determinations are not "quite minor matters" -- they address the very purpose of the survey and enforcement system.

1. Issuance Of Deficiencies Without Imposition Of A Remedy

In some cases, surveyors cite deficiencies based upon findings at the facility, but HCFA does not impose a remedy, either because the deficiency was found to be corrected

⁶ Pursuant to 42 U.S.C. § 1395i-3(g)(1), states are responsible for certifying skilled nursing facility compliance with Medicare standards.

promptly or it did not rise to the scope or severity for which a remedy was deemed appropriate. See 59 Fed. Reg. 56,116, 56,164 (Nov. 18, 1994) ("there are situations in which a remedy might not be necessary because the facility corrected the practice which led to the abuse."). In such cases, the determination that a deficiency existed is not appealable -- even if the provider vigorously disputes the accuracy of the citation and seeks only to correct its compliance record.⁷ Further, where HCFA or the state agency threatens to impose a remedy that is ultimately not imposed, a provider is nevertheless powerless to appeal the citation. *Ruth Taylor Inst.*, No. C-96-100, DAB-CR430 (Aug. 21, 1996) reprinted in Medicare & Medicaid Guide (CCH) ¶ 44,760. The only way a facility may challenge a deficiency citation for which no remedy is imposed is to refuse to submit a plan of correction and to refuse to correct the alleged deficiency, thereby risking termination of its Medicare provider agreement -- hardly an acceptable option.

While the Secretary apparently believes that it is reasonable to preclude review on the grounds that the absence of a remedy equates to the absence of any harm, the reality is that such determinations can and do have significant future ramifications. First, every Medicare and Medicaid certified nursing home in the country must post its statement of deficiencies in a location that is easily

⁷ 42 C.F.R. § 498.3(d)(1); *Schowalter Villa*, No. C-98-493, DAB-CR568 (Jan. 25, 1999); reprinted in Medicare & Medicaid Guide (CCH) ¶ 120,037, aff'd, DAB-1688 (App. Div. May 5, 1999); *Rafael Convalescent Hosp.*, No. C-96-292, DAB-CR444 (Nov. 19, 1996), reprinted in Medicare & Medicaid Guide (CCH) ¶ 45,008, aff'd, DAB-1616 (App. Div. Mar. 24, 1997), app. filed at Doc. No. 97-1967 (N.D. Cal. May 23, 1997); *Arcadia Acres, Inc.*, No. C-96-160, DAB-CR424 (June 26, 1996), reprinted in Medicare & Medicaid Guide (CCH) ¶ 44,513; aff'd, No. A-96-183, DAB-AD1607 (Jan. 22, 1997) reprinted in Medicare & Medicaid Guide (CCH) ¶ 45,140; *Fort Tyron Nursing Home*, No. C-96-173 (July 3, 1996).

accessible to its residents (e.g., in the lobby). 42 C.F.R. § 483.10(g)(1); U.S. Department of Health and Human Services, Medicare/Medicaid State Operations Manual, HCFA Pub. 7 Rev. 1 (3/98) App. PP-25 (hereinafter, "HCFA Pub. 7"). By statute, statements of deficiencies must also be disclosed to the public by HCFA and state survey agencies.⁸ 42 U.S.C. § 1395i-3(g)(5). Moreover, statements of deficiencies now are publicly disclosed on HCFA's internet website.⁹ The website publicizes all deficiencies for which a home was cited, including isolated deficiencies that constitute no actual harm. Provider comments regarding the deficiencies are not provided on the website, and although the website contains a column to identify the date a facility has corrected a deficiency, those dates frequently are missing. The widespread public availability of inaccurate, unbalanced, or misleading deficiency data -- at the facility itself, from the state survey agency, and on the internet -- serves to harm the facility and mislead those beneficiaries or family members who seek accurate information on a facility's compliance record.

Second, by statute, deficiencies characterized as substandard quality of care¹⁰ on three consecutive annual

⁸ In some cases, the state survey agency must disclose deficiencies to the state's long-term care ombudsman and must notify a resident's treating physician and the state's nursing home administrator licensing board of the facility's noncompliance. 42 U.S.C. § 1395i-3(g)(5).

⁹ The website is located at www.medicare.gov/nursing/home.asp.

¹⁰ "Substandard quality of care" is defined as one or more deficiencies related to the requirements of participation for resident behavior and facility practices, quality of life, or quality of care that constitute (i) immediate jeopardy to residents, (ii) a pattern of or widespread actual harm that is not immediate jeopardy, or (iii) a widespread potential for more than minimal harm but less than immediate jeopardy with no actual harm. 42 C.F.R. § 488.301.

surveys require a ban on payment for new admissions. 42 U.S.C. § 1395i-3(h)(2)(D). If no remedy is imposed for two limited substandard quality of care citations, and the facility receives a third such citation, the ban on payment for new admissions is imposed automatically. Thus, a very significant penalty can be imposed on a facility when the underlying deficiencies cannot be challenged.

Third, past deficiency citations, regardless of their scope or severity, often affect which enforcement remedy the government chooses to impose after a subsequent survey. In choosing a remedy, HCFA and state agencies are authorized to consider a facility's history of noncompliance, both in general and with respect to the specific deficiencies cited in the current survey. 42 C.F.R. § 488.404(c)(2). There is no limit on the number of years of deficiency data that HCFA can consider in determining the enforcement remedy. Thus, unrelated deficiency citations that occurred several years earlier can be used to justify a more severe penalty against a provider that is now powerless to contest the underlying deficiencies at issue.

Fourth, past deficiencies for which no remedy was imposed can cause a facility to be designated a "poor performing facility" ("PPF"). See, e.g., *Baltic Country Manor*, No. C-96-295 (Dec. 11, 1996), reprinted in Medicare & Medicaid Guide (CCH) ¶ 45,038. A PPF is defined in the HCFA State Operations Manual as "a facility with a history of going in and out of compliance or a facility that has no system in place to monitor its own compliance." HCFA Pub. 7 § 7304B. Unlike facilities without such a designation, PPFs have no opportunity to correct deficiencies prior to the recommendation of the imposition of CMPs or other remedies. *Id.* A facility may be designated a PPF if significant noncompliance is found during the current survey

and Level A deficiencies¹¹ were identified in one of the facility's two most recent standard surveys.¹² HCFA currently is developing criteria for identifying poor performing nursing home chains, and it has recommended that states designate a facility as a PPF if another facility within the same chain -- regardless of its location or its separate corporate or licensure status -- has been designated a PPF.¹³ Thus, PPF designation, especially when based on citations that cannot be appealed by a provider, has a particularly detrimental "domino effect" on other facilities within the same chain that suffer from even relatively minor deficiencies. Chain facilities would have no ability to appeal a related facility's PPF designation or the deficiencies that formed the basis for that designation.

The Secretary's Departmental Appeals Board ("DAB"), which hears provider appeals of adverse survey and enforcement determinations, has refused to permit appeals of prior, uncontested deficiencies that served as a basis for PPF designation. In *Baltic Country Manor*, No. C-96-295 (Dec. 11, 1996), reprinted in Medicare & Medicaid Guide (CCH) ¶ 45,038, a facility was designated a PPF based on the results of a February 1996 survey and its two previous surveys in 1994 and 1995. The facility was never

¹¹ A Level A deficiency is the least serious type of deficiency. A Level A deficiency results in no actual harm, and although it must be corrected, it is not even required to be addressed in a facility's plan of correction.

¹² Standard surveys must be conducted at least once every 15 months. 42 U.S.C. §1395i-3(g)(2)(A)(iii)(I).

¹³ Memorandum from Richard P. Brummel, Acting Director, Disabled and Elderly Health Programs Group, Center for Medicaid and State Operations, to Associate Regional Administrators and State Agency Directors (Sept. 22, 1998).

provided a hearing on the 1994 and 1995 survey deficiencies, which were corrected without the imposition of a CMP, and it therefore sought to contest those deficiencies on the grounds that they contributed to HCFA's imposition of a CMP in the 1996 survey. The ALJ rejected the facility's argument, prohibiting the facility from contesting the earlier deficiencies in an effort to challenge its designation as a PPF. Moreover, the ALJ held that the facility's PPF designation could not be appealed because it was not a reviewable "initial determination" as defined at 42 C.F.R. § 498.3(b).

Significantly, despite the serious consequences of the PPF designation and its relationship to nonappealable deficiency citations, the designation is not authorized by statute or regulation. It was promulgated without public notice or comment and appears only in the State Operations Manual, which is published by HCFA to provide guidance to surveyors. In the case at bar, Illinois Council has challenged the validity of the State Operations Manual on the grounds that it should have been promulgated under the Administrative Procedure Act. As is quite evident in *Baltic Country Manor*, HCFA likes to have its cake and eat it, too -- it will require providers to exhaust administrative remedies, but it then uses informal manual guidance to conveniently circumvent the fair hearing procedures that provide the only forum for review of HCFA and state surveyor actions.

The future ramifications inherent in the citation of deficiencies for which no remedies are imposed are further compounded by the absurdity of many deficiencies. Examples of unreasonable deficiencies include the following:

- (i) A deficiency was cited for use of non-certified staff to make beds, transport patients in wheelchairs, label a pair of glasses for a resident, and organize a patient's clothing, all of which the

surveyor believed constituted a "direct caregiving activity."

- (ii) A D-level deficiency (*i.e.*, an isolated deficiency resulting in no actual harm but with the potential for more than minimal harm and less than immediate jeopardy) was cited because the activity goals for a blind resident who was very interested in sailing and related hobbies "did not include any activities that involved sailing or nautical issues" and because the facility failed to provide a table for the resident to use for building model ships.
- (iii) A G-level deficiency (*i.e.*, a deficiency causing actual harm to a resident) was imposed for violating a resident's dignity by causing him or her to wait in line for a whirlpool bath.
- (iv) A G-level citation was imposed for failure to provide notice to the resident's physician of a change in the resident's condition, even though the facility phoned the physician and the physician personally examined the resident the next day.

Far too often, facilities receive citations for clerical or documentation issues even where there is no allegation of any adverse impact on resident health and safety. In other instances, surveyors impose their own subjective view as to whether the resident was, or could have been, harmed by the facility's conduct, even where the resident and family members expressed no concern. It is unconscionable that providers can be subject to harsh enforcement remedies, "PPF" status, and the widespread public disclosure of their compliance records on the basis of unrelated or absurd

deficiencies for which administrative and judicial review is completely foreclosed.

2. Government's Choice Of Remedy

A nursing facility may not challenge the particular remedy imposed on it by HCFA. 42 C.F.R. § 498.3(d)(11), (14). The DAB frequently has refused to review HCFA's choice of remedy. For example, in *Somers Manor Nursing Home, Inc.*, No. C-96-054, DAB-CR420 (June 4, 1996), reprinted in Medicare & Medicaid Guide (CCH) ¶ 44,517, the facility had been advised incorrectly by the state agency that a particular deficiency had been deemed corrected. Unfortunately, the state agency failed to notify the facility of its erroneous advice in sufficient time to permit the facility to correct the deficiency before the applicable deadline. HCFA nevertheless imposed the remedy of denial of payment for new admissions. The ALJ held that HCFA was not estopped from imposing this severe penalty and noted that ALJs have no authority to review the government's choice of remedy. Similar cases abound. E.g., *Beverly Health & Rehabilitation-Springhill*, No. A-99-19, DAB-CR553 (Oct. 27, 1998) reprinted in Medicare & Medicaid Guide (CCH) ¶ 120,033; *Orchard Grove Extended Care Ctr.*, No. C-97-555, DAB-CR541 (July 20, 1998), reprinted in Medicare & Medicaid Guide (CCH) ¶ 120,006; *Brighton Pavilion*, No. C-96-081, DAB-CR510 (Dec. 10, 1997). Consequently, providers may be subject to excessively harsh remedies, and similarly situated providers may receive very different remedies for the same infractions. Nevertheless, providers have no mechanism to challenge the arbitrary nature of remedy determinations.

3. Level Of Noncompliance Determinations

The severity or level of noncompliance affects HCFA's choice of remedy. The state agency determines the level of noncompliance by considering (i) whether a facility's deficiencies constitute actual harm or immediate jeopardy and (ii) whether the deficiencies are isolated or constitute a pattern or are widespread. 42 C.F.R. § 488.404(b). The remedies are divided into three groups, Categories 1, 2, and 3, with the least severe remedies (e.g., directed plan of correction) in Category 1 and the most severe remedies (e.g., immediate termination) in Category 3.

CMPs may be imposed as Category 2 or Category 3 remedies. Depending on the severity of the deficiency, a CMP may range from \$50 - \$3,000 per day or from \$3,050 - \$10,000 per day. 42 C.F.R. § 488.438(a).¹⁴ The penalty amount is based on the facility's history of noncompliance (including repeat deficiencies, the facility's financial condition, and the facility's degree of culpability). *Id.* § 488.438(b).

A nursing facility may not challenge a finding as to the level of noncompliance, unless a successful challenge on the issue would (i) affect the range of CMP amounts that

¹⁴ The Secretary recently issued a regulation which purports to establish CMPs "per instance" of noncompliance. 64 Fed. Reg. 13,354 (Mar. 18, 1999) (codified at 42 C.F.R. §§ 488.402 *et seq.*). The American Health Care Association has challenged the Secretary's authority to issue this rule on the grounds that "per instance" CMPs violate the Medicare and Medicaid statutes and the Administrative Procedure Act. *American Health Care Ass'n v. Shalala*, Case No. 1:99 CV 01207 (D. D.C. May 18, 1999).

¹⁵ The loss of approval to provide nurse aide training programs is a Category 1 remedy. 42 C.F.R. § 488.408(c).

HCFA could collect, or (ii) affect a finding of substandard quality of care that results in the facility's loss of approval to provide in-house nurse aide training programs.¹⁵ 64 Fed. Reg. 39,934 (July 23, 1999).

Although some level of compliance determinations are now subject to review, virtually all such determinations have a significant effect on the facility, especially financially. Moreover, level of compliance determinations are not imposed in a consistent manner among providers because so many of the terms used to define the levels of compliance are vague (e.g., "actual harm," "more than minimal harm," "widespread actual harm that is not immediate jeopardy," "widespread potential for more than minimal harm, but less than immediate jeopardy with no actual harm"). Illinois Council has challenged the vagueness of these regulations, but no individual provider could ever bring such a challenge in the current administrative review process. The vagueness of the standards by which providers are judged -- and judged harshly -- should not be left to chance interpretation by individual HCFA officials or state surveyors.

C. Even When Administrative Or Judicial Review Is Available, The Secretary's Procedural Or Other Requirements Strongly Discourage Such Review

The Secretary has created such significant incentives for providers to waive their appeal rights that meaningful review is effectively precluded. For example, the Secretary's strict pleading requirements -- with no support in the regulations -- are one way that the Secretary prevents providers from challenging deficiencies imposed under the facility survey, certification, and enforcement system. According to applicable regulations, a request for hearing is only required to identify the "specific issues, and the findings of fact and conclusions of law with which the affected party disagrees; and . . . specify the basis for

contending that the findings and conclusions are incorrect." 42 C.F.R. § 498.40(b). However, on HCFA's motions for summary affirmance of the remedy imposed, hearing requests specifying the issues using notice pleading rules have been deemed insufficient. E.g., *Care Inn of Gladewater*, DAB-1680 (requesting review of "the alleged noncompliance with certification requirements that lead to the threatened enforcement"); *Birchwood Manor Nursing Ctr.*, No. A-98-66, DAB 1669 (Sept. 4, 1998) reprinted in Medicare & Medicaid Guide (CCH) ¶ 120,023 (requesting a hearing to "contest the remedies, certification issues, and any and all remedies and adverse actions recommended as a result of the . . . survey").

In addition, the time-consuming nature of the administrative review process further discourages providers from appealing adverse determinations. As noted above, there is no expedited review process for the issues raised by Respondent in this case. Moreover, appeals are not prioritized in any way (except for those involving the imposition of immediate provider termination). Consequently, a broad regulatory or statutory challenge such as this -- even if it were subject to administrative review, which *Amici* do not concede -- will be reviewed with all other appeals on a "first-in-first-out" basis. Given the amount of time required to obtain a decision from the DAB, providers frequently decide not to appeal at all, or they discontinue the appeal process at the DAB level. Our research revealed only two cases involving a constitutional or regulatory challenge to HCFA practices and policies that was reviewed in federal court: *Rafael Convalescent Hosp. v. Shalala*, No. C 97-1967 FMS, 1998 WL 196469 (N.D. Cal. Apr. 15, 1998) (denying government's motion for summary judgment with respect to provider's allegations that regulations were not promulgated in accordance with Administrative Procedure Act and that HCFA failed to follow internal guidelines before sanctioning provider); and *Ivy Hall Geriatric & Rehabilitation Ctr., Inc. v. Shalala*, No.

CIV. AMD 98-2666, 1999 U.S. Dist. LEXIS 8677 (D. Md. May 25, 1999) (granting defendant's motion for summary judgment regarding constitutionality of appeal procedures for revocation of facility's authorization to conduct nurse aide training programs).

III. Permitting Pre-Enforcement Judicial Review Of Respondent's Case Is Consistent With The Purposes Of The Doctrine Of Exhaustion Of Administrative Remedies

The purpose of the doctrine of exhaustion of administrative remedies is to (i) prevent premature interference with agency process, (ii) to afford the agency an opportunity to correct its own errors, (iii) to provide the parties and the courts the benefit of agency expertise, and (iv) to compile a record for judicial review. *Salfi*, 422 U.S. at 765 (1975). None of the purposes of the doctrine would be satisfied if this Court were to require Respondent's members to contest individually, and in piecemeal fashion, the regulatory scheme at issue in this case.

First, pre-enforcement judicial review of regulatory challenges does not constitute premature interference with agency process, where, as here, the administrative agency has no authority to address statutory or constitutional issues. As this Court recognized in *Mathews v. Eldridge*, it is unrealistic to expect that the Secretary would consider substantial changes in the current administrative review system at the behest of a single provider raising a constitutional challenge in an adjudicatory context. 424 U.S. at 330. The futility of exhaustion in such a case is obvious.

Second, Respondent's challenge is not within the scope of administrative expertise. Constitutional and statutory challenges are considered to be within the scope of judicial competence. *Salfi*, 422 U.S. at 767; *Thunder Basin Coal Co.*, 510 U.S. at 215.

Third, the parties cannot compile a record to assist later judicial review when the administrative review process precludes consideration of regulatory and statutory challenges. Because the administrative review process does not address the broad challenge at issue here, this Court should not relegate review of this matter to a process that cannot produce an adequate record for review. *See McNary*, 498 U.S. at 493. The adequacy of the record for review is particularly critical in this case, where, as here and in *McNary*, some administrative determinations are appealed directly to a circuit court of appeals.

Finally, denying jurisdiction in this case and requiring Respondent's members to individually appeal what could be accomplished in a single ruling serves only (at best) to consume the resources of an already overburdened administrative appeal system. At worst, Respondent's legitimate constitutional and statutory challenges will never receive meaningful review, and the Secretary will possess the absolute power -- unfettered administrative discretion -- that corrupts so absolutely.

CONCLUSION

The judgment of the Court of Appeals for the Seventh Circuit should be affirmed.

Respectfully submitted,

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